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The Global Newsletter on Pharmaceutical Medicine

IFAPP

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS AND PHARMACEUTICAL MEDICINE

The only international organisation for everyone involved in Pharmaceutical Medicine

THIS ISSUE:

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Pharmaceutical Medicine Specialty Training in the UK

Faculty of Pharmaceutical Medicine

Advancing the science and practice of pharmaceutical medicine for the benefit of the public

Preview of ICPM 2022 Session, 19 October 2022, 17:15-18:00, Athens time

The Faculty of Pharmaceutical Medicine (FPM) is the UK's self-governing, standard-setting body for the medical specialty of pharmaceutical medicine which was founded in 1989 as a faculty of the three Royal Colleges of Physicians of the United Kingdom

2022 marks the 20th anniversary of pharmaceutical medicine as a recognised UK medical specialty and the implementation of Higher Medical Training (HMT) in pharmaceutical medicine – the predecessor to Pharmaceutical Medicine Specialty Training (PMST). In May 2021, the General Medical Council approved FPM's new curriculum which has been enriched from the experience gained from the implementation of PMST during the last 20 years. This presentation will provide an update on the new PMST curriculum, how trainees will benefit from the new focus on in-work capability and FPM's plans to support the training and education of the next generation of pharmaceutical physicians.

Session Chair:

Dr Brigitte Franke-Bray

Speakers:

Prof Peter Stonier

Dr Jaya Chidambaram

Continuing Education in Pharmaceutical Medicine – Asian Expectation of New Education and Training for All in Pharmaceutical Medicine

Preview of ICPM 2022 Virtual-only Session, 20 October 2022, 11:00-12:30, Athens time

The education in pharmaceutical medicine has been the foundation of IFAPP activities and many courses are recognised by international organisations such as the PharmaTrain Federation. The learning opportunities, however, are largely centred in European regions, and expansion to wider geographic areas is expected.

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In addition, patient engagement has become a high priority for all stakeholders pursuing unmet medical needs. Also expected is the education to meet rapidly advancing technologies such as gene editing, regenerative medicines, new vaccine development and evolving digital innovation supporting analysis of real-world evidence, as well as health technology assessment.

In our session, we will introduce the status of the PharmaTrain Centre of Excellence programme in Japan, followed by the on-going effort in the Philippines for their course recognition. Expectations in medical affairs in Australia will be shared, in addition to the training provided by MAPS globally, and discussion of potential collaboration with MAPS will follow.

SPEAKERS:

- Kotone Matsuyama (m-kotone@nms.ac.jp)
  Professor, Department of Health Policy and Management,
  Deputy Director, Center for Strategic Research Initiative, Nippon Medical School
  Director, Board Certified Member of JAPhMed (The Japanese Association of Pharmaceutical Medicine).
  Board of Officers, IFAPP (International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine)

- Dr Jonas D Policarpio (jdpolicarpio@unilab.com.ph)
  Director, Medical and Regulatory Group, UNILAB, Inc Consumer Health
  Immediate Past President, PCPM (Philippine College of Pharmaceutical Medicine)

- Dr Matt Britland (mattybritland@gmail.com)
  Medical Director/Amgen
  President, APPA (Australian Pharmaceutical medical and scientific Professional Association)

- Dr Victoria Elegant (velegant@amgen.com)
  MBBS, DRCOG, FPM, FFPM, Adjunct Professor
  Vice President, Medical Affairs, Amgen Asia Pacific
  Global Lead, Access to Medicines, Amgen
  President Asia Pacific, Medical Affairs Professional Society
  Advisor, FPM Global

CO-CHAIRS:

- Dr Kyoko Imamura (kimamura1@live.jp)
  President, Japanese Institute for Public Engagement,
  Visiting Professor, Social Cooperation Program of IT Healthcare, Graduate School of Pharmaceutical Sciences, The University of Tokyo
  Past President, IFAPP (2018-2020)

- Dr Victoria Elegant (velegant@amgen.com)
  MBBS, DRCOG, FPM, FFPM, Adjunct Professor
  Vice President, Medical Affairs, Amgen Asia Pacific
  Global Lead, Access to Medicines, Amgen
  President Asia Pacific, Medical Affairs Professional Society
  Advisor, FPM Global

Kotone Matsuyama

Dr Jonas D Policarpio

Dr Matt Britland

Dr Victoria Elegant

Dr Kyoko Imamura

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Institutional Research Governance

Preview of hybrid ICPM 2022 session, 20 October 2022, 11:00-12:30, Athens time

Chairs:
Chieko Kurihara, BSocSc, specially appointed Professor, Kanagawa Dental University, and Member of the IFAPP Ethics Working Group

Takis Vidalis, Lawyer, PhD in Law, Senior Advisor National Bioethics Committee of Greece, BioMedLex Coordinator

Topics and Speakers:
1. 'Association for the Accreditation of Human Research Protection Programs (AAHRPP): Institutional governance for protecting research participants, including IRB'

Elyse I. Summers, JD, President and CEO AAHRP, United States

2. 'CIOMS Principles of Good Governance for Research Institutions (PGGRI) for research integrity'

Dr. Dominique Sprumont, Professor, University Neuchatel, Chairman Research Ethics Committee of the Canton of Vaud, Switzerland, CIOMS working group on Principles of Good Governance for Research Institutions (PGGRI)

3. 'Governance of biobank (and health database), under the Bioethics and Safety Act in Korea'

Summary:
In the conduct of research, one should not seek to achieve the direct goal of obtaining scientific fruits. The fruits of new research should be obtained in accordance with the conscience inherent in the researchers themselves and under proper governance.

Recently, in large research projects, humanities and social science researchers from law, political science, ethics, philosophy, communication, health care systems, etc. are often added to address ELSI (Ethical, Legal and Social Implications) and research governance for new technologies.

In this session, three governance-oriented speakers will share the latest status of topics related to human subjects' protection and organisational governance for clinical trials, research governance efforts in research institutes, and research governance efforts in biobanks.

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Real World Data in Pharmacoepidemiology and Opportunities for Real World Evidence

Preview of ICPM 2022 Session, 20 October 2022, 12:30 – 13:30, Athens time

Abstract:
Real World Data (RWD) are clinical data gained in the day-to-day treatment of patients. They may complement data from controlled clinical studies and are increasingly used for the evaluation of the use of medicinal products in real life, the epidemiology of diseases and the safety and effectiveness of medicinal products. They may also support the recruitment of patients into clinical studies and, together with the aid of wearables, can provide transferable health data. The quality of RWD is of vital importance.
This session will address the quality of RWD as an important factor as well as the MHRA guidance on the use of RWD in clinical studies to support regulatory decisions. The use of RWD and real-world evidence (RWE) in the EU Medicines Regulation will be presented through the EMA's vision that, *"by 2025, the use of RWE will have been enabled and its value will have been established across the spectrum of regulatory use cases (...) in order to support the development and use of better medicines for patients"* and its implementation in the DARWIN EU network (1).

1 Peter Arlett et al. Real-world evidence in EU medicines regulation: Enabling use and establishing value. Clinical Pharmacology & Therapeutics, Volume 111, Number 1, January 2022

Chairs:
Elena Panitti, MD, Global Head RWE Excellence, Novartis, Switzerland
Brigitte Franke-Bray, MD PhD FFPM GFMD, Treasurer IFAPP

Topics and speakers:

Quality in the RWD initiative in Austria
Johannes Pleiner-Duxneuner (MD PhD), President GPMed (Austria)

MHRA guidance on the use of real-world data in clinical studies to support regulatory decisions
David Brown, Statistician, Medicines and Healthcare products Regulatory Agency (UK)

A vision for use of real-world evidence in EU medicines regulation: the DARWIN EU network
Xavier Kurz, Head of Data Analytics, Workstream Data Analytics and Methods Task Force, European Medicines Agency (The Netherlands)

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Newly Emerging Ethical Issues with Data-Driven Research and Data Sharing

Preview of ICPM 2022 session, 20 October 2022, 14:30-16:00, Athens time

Chairs:
Kotone Matsuyama, Professor, Department of Health Policy and Management, and Vice President of Center for Strategic Research Initiative, Nippon Medical School & IFAPP Ethics Working Group Chair

Varvara Baroutsou, MD, PhD, GFMD, EMAUD, President EL.E.F.I., IFAPP President-Elect

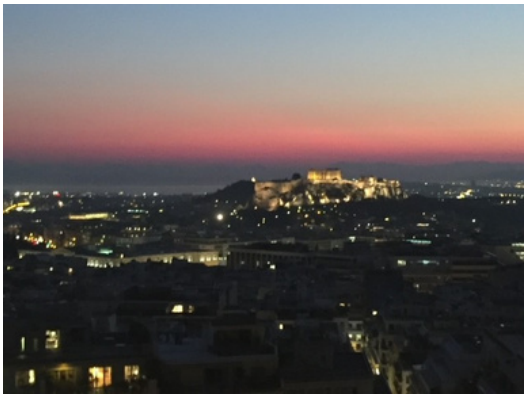
Topics and Speakers:
1. The WMA's Declaration of Taipei, the EU's GDPR, and the EMA's Policy 0070: The Impact of Ethics, Law, and Policy on Data Sharing Practices in Europe
Francis P. Crawley, BPhil., Executive Director, Good Clinical Practice Alliance (GCPA) & SIDCER (tbc)

2. Current Situation and Issues with the Data-Driven Research in Japan
Chieko Kurihara, BSocSc, specially appointed Professor, Kanagawa Dental University, and Member of the IFAPP Ethics Working Group

3. Current Situation and Issues with the Data-Driven Research in the US
Laura Biven, PhD, Branch Chief for Integrated Infrastructure and Emerging Technologies Office of Data Science Strategy Division of Program Coordination, Planning and Strategic Initiatives Office of the Director National Institutes of Health

The session theme:
New Technologies & Bioinformatics/Data science/Data analytics
Ethical, Legal, Social issues
RWD/Real World Evidence/Big Data/Pharmacoepidemiology
New Technologies & Bioinformatics/Data science/Data analytics

In clinical trials and clinical studies, new approaches such as data sharing to utilise existing data have recently been initiated. On the other hand, ethical issues related to the protection of subjects and data handling have arisen that could not be anticipated in conventional clinical trials and clinical research.



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Young Professionals: How to Establish and Boost Your Career in Pharmaceutical Medicine

Preview of ICPM 2022 Session, 20 October 2022, 18:00-19:00, Athens time

In 2021, IFAPP established the Young Professionals Working Group (YPWG), dedicated to professionals in Pharmaceutical Medicine that are under 40 years old. Its main objective is to promote educational opportunities in the field of medicines development and to foster the career progression of our younger colleagues.

Speaking to young professionals has shown us that becoming aware of one's interests and strengths in the wider field of Pharmaceutical Medicine can be challenging.

The YPWG aims to share the expertise of senior professionals and to help young colleagues find the ideal working environment alongside developing their own skills and competences in medicines development. An important objective is also to recruit young members from national member associations so that different cultural and scientific backgrounds can meet, and knowledge be exchanged. Thus, the YPWG aims to identify the best opportunities for education and growth and to support young professionals in facing the different issues they will encounter during their professional lives as they build their careers.
ICPM 2022 is an excellent opportunity for networking with Pharmaceutical Medicine professionals of all backgrounds at an international level and to start working together for a common benefit: our health.

Chairs:

Annette Mollet, PhD, dipl. Pharm. Med., MBA, GFMD, IFAPP Board Member, Chair of Young Professionals WG

Marco Romano, MD, PhD GFMD, IFAPP President

Speaker:

Nikolaos Tsokanas, BSc (Hons), MSc, MBA, Medical Operations & Quality Systems Cluster Head Bayer (GR, CY, BG, MD, RO, Ukraine)

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New Publication of the IFAPP Ethics Working Group

Sandor Kerpel-Fronius, Chieko Kurihara, Francis P. Crawley, Sander Becker, Brigitte Franke-Bray, Kotone Matsuyama, Shehla Naseem and Johanna Schenk, all members of the IFAPP Ethics Working Group, expanded on "The ethical responsibility to continue investigational treatments of research participants in situation of armed conflicts, economic sanctions or natural catastrophes" as published in Front. Med., 09 August 2022, Sec. Regulatory Science. The full paper can be accessed here.

frontiers | Frontiers in Medicine

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Check for updates

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SPECIALTY SECTION
This article was submitted to Regulatory Science, a section of the journal Frontiers in Medicine

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The ethical responsibility to continue investigational treatments of research participants in situation of armed conflicts, economic sanctions or natural catastrophes

Sandor Kerpel-Fronius[1*†], Chieko Kurihara[2†], Francis P. Crawley[3†], Varvara Baroutsou[4†], Sander Becker[5†], Brigitte Franke-Bray[6†], Kotone Matsuyama[7†], Shehla Naseem[8†] and Johanna Schenk[9†]

[1]Department of Pharmacology and Pharmacotherapy, Semmelweis University, Budapest, Hungary, [2]Kanagawa Dental University, Kanagawa, Japan, [3]Good Clinical Practice Alliance—Europe (GCPA) & Strategic Initiative for Developing Capacity in Ethical Review, Leuven, Belgium, [4]Consultant, Pharmaceutical Medicine, Athens, Greece, [5]Consultant in Pharmaceutical Medicine, Dover Heights, NSW, Australia, [6]Independent Consultant, Basel, Switzerland, [7]Department of Health Policy and Management, Nippon Medical School, Tokyo, Japan, [8]Ferozsons Laboratories Ltd, Karachi, Pakistan, [9]PPH plus GmbH & Co. KG, Hochheim am Main, Germany

Author: **Dr. med. Johanna Schenk**, FFPM GFMD, on behalf of the IFAPP Ethics Working Group

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First Webinar: PharmaTrain Recognition of Individual Courses or "Centre of Excellence Recognition" for Academic, Commercial and Non-commercial Training Organisations

As of September, IFAPP will offer a series of highly practice-relevant bi-monthly webinars

SAVE THE DATE
Tuesday, 27 September 2022, 2:00 pm – 3:30 pm CET
Please register here.

This webinar will address the successful collaboration between IFAPP and PharmaTrain towards global quality in education in Pharmaceutical Medicine by presenting the "PharmaTrain Recognition" for individual courses or "Centre of Excellence Recognition" for academic, commercial and non-commercial training organisations fulfilling shared quality standards.

Research and Development of new treatments is occurring globally but there is no global concept and institution for education and training of the scientists involved in the development process of new medicines nor is there a global process for quality recognition of educational courses.
PharmaTrain aims at filling this void: PharmaTrain defines syllabus, learning outcomes, curricula and competencies for post-graduate education and training programmes covering all areas of the "PharmaTrain Syllabus of Pharmaceutical Medicine" through its highly experienced course providers and training experts.

The quality standards jointly developed by course providers, pharmaceutical industry training experts and scientists in international not-for-profit organisations during the IMI (1) project "PharmaTrain" are applied now by the not-for-profit organisation "PharmaTrain Federation".

Harmonisation and certified quality of education in Pharmaceutical Medicine are an important pre-requisite for the successful development of this discipline and fit-for-purpose education of all scientists involved in the more and more complex environment of medicines development.

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This webinar will give an understanding of the objectives and achievements of the joint initiative of IFAPP and PharmaTrain with regard to improving post-graduate education in Pharmaceutical Medicine on a global basis, the benefits for course providers when joining this initiative and the detailed process for achieving a ***PharmaTrain Centre of Excellence Award.***

In a subsequent webinar in November the experience of Pharmaceutical Medicine course providers in the preparation and execution of a PharmaTrain assessment will be presented and discussed.

Author: **Ingrid Klingmann** MD PhD FFPM GFMD, President PharmaTrain Federation

Call for Candidates for IFAPP President–Elect

IFAPP is encouraging members of National Member Associations and Individual Affiliates to consider joining the IFAPP Board and becoming a candidate for the role of President–Elect. The election will take place at the House of Delegates meeting planned on the occasion of IFAPP's next International Conference on Pharmaceutical Medicine (ICPM 2022) in Athens, Greece (https://www.icpm2022.gr/programme/), on 21 October 2022.

If you are interested, please send a Letter of Application to Dr Anna Jurczynska, the IFAPP Board Secretary (romanek.jurczynska@gmail.com).

Candidacy must be communicated by the respective National Member Association or by the Individual Affiliate to the Board's Secretary at least four (4) weeks prior to the date on which the election is planned, ie, no later than on 23 September 2022.

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2022 IFAPP Asian Regional Meeting at JAPhMed Annual Conference

Conference Report

Since 2016, JAPhMed has been offering a part of its annual scientific meeting as a platform for the IFAPP Asian regional meeting. This year, a session 'The Medical Affairs (MA) role in Asian regions - Learn from experiences of APPA (Australian Pharmaceutical medical and scientific Professionals Association) and MAPS (Medical Affairs Professional Society)' was developed inviting speakers from both organisations. An interactive discussion was realised thanks to the enthusiastic audience which attracted nearly 150 participants until the last minutes of this session. The discussion spanned from similarities and differences of the vision/mission and services provided by APPA and MAPS, to the common issues of making Medical Affairs activities visible and independent, and efforts paid to make it supported by regulatory authorities, clinical stakeholders and patient groups. The presentation inspired the audience and active questions & answers were exchanged during the session.

The seminar adjourned with the information about ICPM 2022 in Athens in October 19-21, 2022 inviting the audience to our Asian meeting agenda as the next opportunity to follow up.

There were also attendees from outside Asia, and Raoul-Dominique Giger, IFAPP Delegate from SGPM, Switzerland provided enthusiastic feedback. He was delighted how fascinating the presentations were and that also the Q&A session was quite exciting. He enjoyed the attendance very much and looks forward to the next Asian meeting.

Screenshots upper row, from left to right: Kyoko Imamura, IFAPP Past-President, Dr. Hahn-Ey Lee, Country Medical Director, Pfizer Japan; lower row, from left to right: Kotone Matsuyama, Chair IFAPP Ethics Working Group, Matt Britland, APPA President

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Theme:
"The Medical Affairs (MA) role in Asian regions – Learn from experiences of APPA (Australian Pharmaceutical medical and scientific Professionals Association)" and MAPS (Medical Affairs Professional Society)

Abstract:
IFAPP (International Federation of Associations of Pharmaceutical Physicians & Pharmaceutical Medicine), a non-profit organisation established in 1975, has national member associations in about 30 countries. The Japanese Association of Pharmaceutical Medicine (JAPhMed) has been a member of IFAPP since its inception. The Asian Regional Meeting of IFAPP will focus on current topics and issues related to pharmaceutical medicine in the countries with member associations in Asian Pacific.
In the last Asian meeting, we agreed that we need education and certification for Medical Affairs professionals (not only Medical Science Liaisons (MSLs) but also Medical Directors, for example), and capability frameworks should be established to develop well qualified MA professionals with certification accredited by established authorities.
Medical Affairs Professional Society is a global organisation founded 6 years ago with a chapter focused in Asia Pacific on Medical Affairs, in particular educational needs, cross-industry networking and focusing on demonstrating the value of Medical Affairs in the region and globally. The APPA has focused their activities on MA/MSL professions. Our colleagues in APPA can share with us the educational needs for MAs and they also guide us on basics of Health Technology Assessment (HTA), upon which we can adapt to national healthcare systems to make our products accountable for the society.

Venue:
Date: Thursday 28th July 2022 at 14:30-15:50 (Tokyo time), 15:30-16:50 (Sydney time).

Agenda:
1) Introduction of the APPA and their activities on the education and certification for Medical Affairs
Dr. Matt Britland, the President of APPA (ca. 20 min)
2) Introduction of the Medical Affairs Professional Society and their educational activities
Dr. Hahn-Ey Lee, Country Medical Director, Pfizer Japan (ca. 20 min)
3) Discussion (ca. 30 min)
4) Introduction of the upcoming ICPM 2022 and Asian session (ca. 10 min)
5) Any other proposals for discussion

Authors:
Kyoko Imamura GFMD, IFAPP Past-President

Kotone Matsuyama GFMD, Chair of the IFAPP Ethics WG

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The Swiss Tropical and Public Health Institute

Introduction

Founded 80 years ago, the Swiss Tropical and Public Health Institute (Swiss TPH) is a world-leading institute in global health with a particular focus on low- and middle-income countries. Associated with the University of Basel, Swiss TPH combines research, education and services at the local, national and international level. About 900 people from 80 nations work at Swiss TPH focusing on infectious and non-communicable diseases, environment, society and health as well as health systems and interventions.
Swiss TPH translates research into action and helps strengthen health systems and policy shaping to generate measurable outputs and create lasting impact for individuals and communities worldwide.

Our clinical trials expertise

With over 20 years of clinical research and operational experience, Swiss TPH has a unique expertise in clinical trials. In line the UN Sustainable Development Goals (SDG) 3, we support research and development of vaccines and medicines for communicable and non-communicable diseases that primarily affect low- and middle-income countries. Together with our partners, we design, implement, manage, build capacity and monitor Phase I to Phase IV clinical trials with a focus on poverty-related diseases. As both a sponsor and service provider, Swiss TPH understands the barriers to delivering clinical trials in difficult settings and offer strategic, customized solutions with the aim to deliver high quality data and patient-centred evidence-based care.

Through our multidisciplinary teams, large network of collaborators and local and global experts, Swiss TPH supports a diversity of clients ranging from the pharmaceutical industry and biotech companies, to Product Development Partnerships, NGOs and academia. Our long-standing expertise allows us to continuously adapt and develop knowledge from both investigator-initiated studies as well as regulatory trials.

Swiss TPH
Swiss Tropical and Public Health Institute

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Figure 1: Unique expertise and network of Swiss TPH

Clinical trial services at Swiss TPH include

- Trial Management of Multinational Studies
- Study Design and Adaptability
- Feasibility and Study Site Evaluation
- Strengthening Capacity Building
- Planning and Conducting of Studies Phase I – IV
- Research Governance and Good Clinical Practice

Project Highlights

ANTICOV

In 2019, African countries and an international network of research institutions, including Swiss TPH, joined forces to launch the largest COVID-19 clinical trial in Africa.

ANTICOV aims to respond to the urgent need to identify treatments that can be used to treat mild and moderate cases of COVID-19 early and prevent spikes in hospitalisation that could overwhelm fragile, overburdened health systems in Africa. Swiss TPH is responsible for the active monitoring of the sites in the Democratic Republic of Congo, providing Good Clinical Practice trainings and co-monitoring for over 13 countries involved in the study. Funding is provided by the German Federal Ministry of Education and Research (BMBF).

TB-PRACTECAL

TB-PRACTECAL, a clinical trial led by Médecins Sans Frontières with partners including Swiss TPH, found that a new all-oral treatment regimen for rifampicin-resistant tuberculosis (RR-TB) is safer and more effective than the current accepted standard of care. These results signal the start of a new chapter for patients who often endure gruelling treatment regimens that have a catastrophic effect on physical and mental health. The trial enrolled 552 patients and took place in seven sites across Belarus, South Africa and Uzbekistan. Swiss TPH was responsible for monitoring the multinational trial.

Pediatric Praziquantel Consortium

In 2021, the Pediatric Praziquantel Consortium completed its pivotal clinical Phase III trial of praziquantel – a potential new treatment option for the estimated 50 million preschool-aged children with schistosomiasis. As a member of the Consortium, Swiss TPH led the implementation of the clinical trials in Côte d'Ivoire and Kenya. The trial, co-funded by the Global Health Innovative Technology Fund and the European & Developing Countries Clinical Trials Partnership (EDCTP), is a major step towards the treatment of schistosomiasis, one of the most damaging parasitic diseases that affects the lives of over 200 million people.

Author: **Elisabeth Reus**, Head of the Clinical Operations Unit, elisabeth.reus@swisstph.ch
https://www.swisstph.ch/activities/clinical-trials/

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- **27 September 2022 - 2.00 - 3.30 PM CET**
  Webinar PharmaTrain Recognition of individual courses or "Centre of Excellence Recognition" for academic, commercial, and non-commercial training organisations
  Please register here.

- **19-21 October 2022**
  ICPM 2022 - Athens, Greece
  Click here for more information and registration.

THE FLAG

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IFAPP Communication Working Group
Ghazaleh Gouya-Lechner (Chair), Varvara Baroutsou, Brigitte Franke-Bray, Anna Jurczynska, Ana Rita Lima, Rita Lobatto, Kotone Matsuyama, Helio Osmo, Joanne Ramsey and Johanna Schenk (IFAPP TODAY Editor-in-chief).

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