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THIS ISSUE

IFAPP President and President Elect

"The House of Delegates meeting confirms the appointment of Dr Marco Romano as IFAPP President and Dr Barbara Baroutsou as IFAPP President Elect: here are their self-presentations"

Dr Marco Romano is Executive Medical Director at Covance since 2007.

In this position, he has full responsibility within the Medical Department including Clinical Development, Medical Support to Clinical Operations, Medical Monitoring and Medical Support to PV Service.

He has over 30 years of pharmaceutical development experience, both in pharmaceutical companies and clinical research organizations.

He has successfully managed several Phase II, III and IV clinical trials, and since 1998 he held senior management positions within the CRO sector such as Country Manager, Medical Director and Chief Medical Officer.

He got his degree in Medicine at the University of Genoa (1983); he then obtained a PhD in Hygiene, Epidemiology and Public Health (1987) and another PhD in Clinical Pharmacology (1994).

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He is co-author of several scientific papers concerning mutagenesis and carcinogenesis, pharmacokinetics and pharmacodynamics of chemical compounds and about glutathione metabolism. He is Member of the Italian Medical Association since 1983 and he has been President of the Italian Society of Pharmaceutical Medicine (SIMeF) from 2014 to 2020. He is now acting as IFAPP President for the term 2020-2022.

Introducing Dr Varvara (Barbara) Baroutsou, Athens, Greece

Barbara is a purpose-driven Medical Doctor & leader passionate about science, research and people.

Barbara studied in Greece, Sweden and France; she worked as Internist & Clinical Investigator in Greece and as Chief Scientific Officer in Clinical Development and Medical Affairs in Western Europe.

She graduated from the Medical School of the University of Athens (UoA) in 1984. Following a scholarship in Respiratory Pathophysiology at the Experimental Respiratory Lab of the UoA, where she completed her PhD, she started her residency in Internal Medicine at the "Amalia Fleming" General Hospital in Athens. Upon successful certification in Internal Medicine, she served as registrar and clinical investigator acquiring experience in clinical research at the "Sotiria" General Hospital of Thoracic Diseases.

After a positive Phase III pivotal clinical trial collaboration, she joined Merck Research Laboratories in 1992 and worked in Clinical Development as responsible for Clinical Research in Middle Europe Region until 2004. During this period, Barbara pursued postgraduate studies in Health Economics at the Stockholm School of Economics in 1998 & and later on moving to Sanofi, as Regional Medical & Scientific Director, she acquired a European Market Access Diploma from the University Claude Bernard Lyon.

In January 2015, she joined Novartis as Chief Scientific Officer in Greece and in June 2016, she was promoted to Chief Scientific Officer for Medical Affairs and Clinical Development in Western Europe until June 2020.

Currently she is an Independent Medical Consultant of Internal Medicine and a Pharmaceutical Medicine, affiliated with Greek Medical Schools' postgraduate programs on Infectious Diseases, Molecular Basis of Human Diseases and Clinical Pharmacology & Therapeutics.

Moreover, Barbara is the President of the Greek-Hellenic Pharmaceutical Medical Society-EL.E.FI. Furthermore, she is an active Member of IFAPP Ethics, External Affairs and Communication Working Groups and in October 2019 she hosted the joint IFAPP& IFAPP Academy Regional meeting for Europe in Athens, Greece. In November 2019 she received the Global Fellow in Medicines Development (GFMD) award by IFAPP & IFAPP Academy. In July 2020 she joined the Core Faculty of European Forum for Good Clinical Practice (EFGCP) and during the last IFAPP House of Delegates Meeting on September 17 she was voted President elect and Member of IFAPP Board of Officers for the period 2020-2022.

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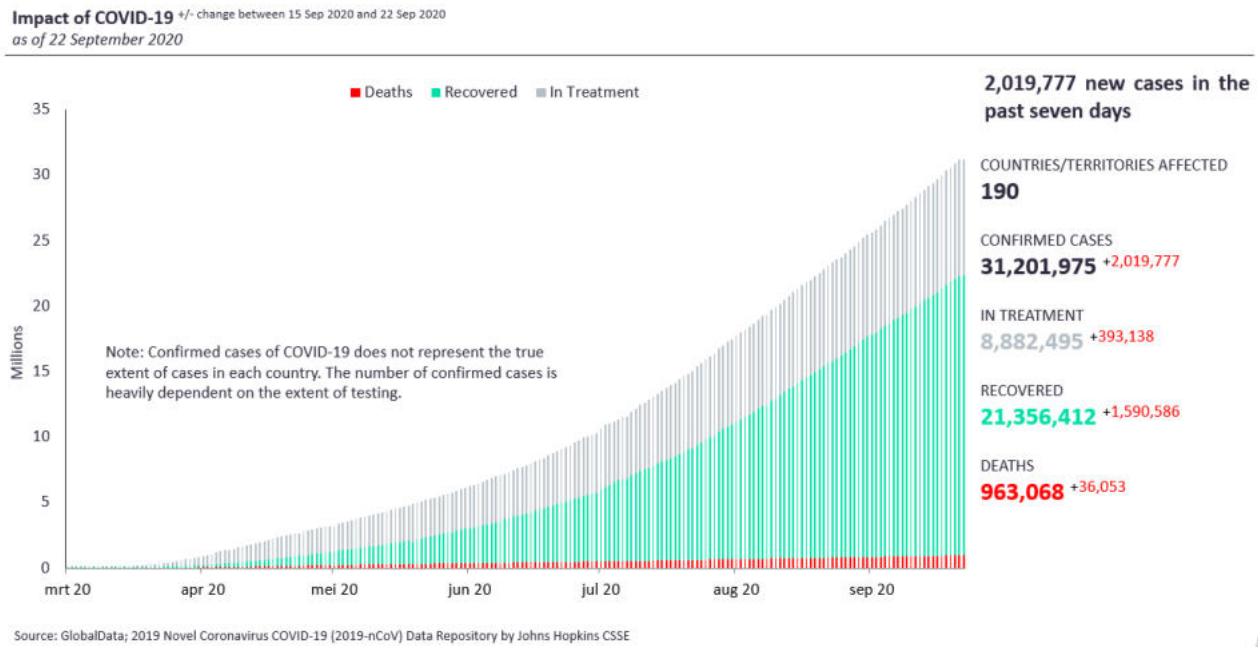
Her major inspiration is collaborating with academia, pharmaceutical medicine experts, clinical investigators, patient associations and regulators, putting patient at the center of R&D and innovation in healthcare agenda for better outcomes. Barbara is a strong believer of the expanded value proposition of Pharmaceutical Medicine, as a discipline bridging Research & Development with the practice of Medicine and patient access to optimal care.

COVID-19 and Vaccine Development

The world is watching the race for COVID-19 Vaccine

The virus has now spread to 190 countries with more than 31 million confirmed cases and more than 963,000 deaths (as at September 22, 2020) and 2,019,777 new cases in the past seven days. The highest official case counts are in the US, India, Brazil, Russia, Peru, Colombia, Mexico, Spain, South Africa, and Argentina (Figure 1). Currently there are 3,258 clinical trials against COVID-19 registered in various registries and promising clinical data are continuing to emerge for COVID-19 vaccines. Figure 2 shows pipeline-stage vaccines identified by the WHO. Some coronavirus vaccines are now in phase 1/2 trials (combination of phases to support accelerated development), for example, in which they are tested for the first time on hundreds of volunteers [1]. Two vaccines (BNT162b1 and BNT162b2) from BioNTech are tested in a combined phase 1/2/3 clinical trial [2].

Figure 1: Infection Rates Continue to Rise



Source: GlobalData; 2019 Novel Coronavirus COVID-19 (2019-nCoV) Data Repository by Johns Hopkins CSSE

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Figure 2

There is a general consensus among regulatory authorities, pharmaceutical companies and patient advocates that approvals or emergency use authorizations for the vaccine candidates should be granted with conclusive positive data on safety and efficacy on prevention of COVID-19 in adults.

The Russian Direct Investment Fund (RDIF) and the Gamaleya National Research Center of Epidemiology and Microbiology reported positive early results from the phase 1/2 clinical trials of the country's registered COVID-19 vaccine, Sputnik V (consisting of two components, a recombinant adenovirus type 26 (rAd26) vector and a recombinant adenovirus type 5 (rAd5) vector, both carrying the gene for severe acute respiratory syndrome coronavirus 2 spike glycoprotein (rAd26-S and rAd5-S) [3, 4]. Only 76 patients were tested in the clinical trials, which led to the registration in Russia, and it will be tested further for effectiveness in post-registration trials. Other consortia are also developing vector vaccines based on human or ape adenoviruses. Among the best known representatives are the coronavirus vaccine candidate Ad26.COV2.S from Johnson & Johnson as well as the candidates Ad5-nCoV from CanSino Biologics and

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AZD1222 from the University of Oxford's collaboration with AstraZeneca. Sputnik V was provisionally approved under the current Decree of the Government of the Russian Federation. Provisional licensure requires a large-scale study, allows vaccination in a consented general population in the context of a phase 3 trial, though allows the vaccine to be brought into use in a population under strict pharmacovigilance, and to provide vaccination of risk groups.

The overall approach by RDIF and the Gamaleya National Research Center of Epidemiology and Microbiology has been generally criticized [5]. In particular, development of an adequate safety database is crucial for regulatory approval and public acceptance of any new vaccine, especially one using a novel technology platform. Harmonization of safety data collection across vaccine candidates maximizes their comparability and value. Standardized templates for collection of key information for benefit–risk assessment of vaccines by technology including nucleic acid, protein, viral vector, inactivated viral and live viral vaccines have been strongly recommended [6].

The most advanced candidates are expected to begin reporting data from pivotal studies over the coming months, which if positive will be used to support accelerated licensure of the first COVID-19 vaccines. Such data will also provide valuable insights for the field and inform ongoing and future development activities aimed not only at controlling the current global pandemic, but also for effectivelong-term immunization strategies against the disease.

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Global Polio Eradication Initiative Applauds WHO African Region For Wild Polio-Free certification

The Africa Regional Certification Commission certified the WHO African Region as wild polio-free after four years without a case. With this historic milestone, five of the six WHO regions – representing over 90% of the world's population – are now free of the wild poliovirus, moving the world closer to achieving global polio eradication. Only two countries worldwide continue to see wild poliovirus transmission: Pakistan and Afghanistan. The Global Polio Eradication Initiative (GPEI) congratulates the national governments of the 47 countries in the WHO African Region for today's achievement.

"Ending wild polio virus in Africa is one of the greatest public health achievements of our time and provides powerful inspiration for all of us to finish the job of eradicating polio globally," said WHO Director General Dr Tedros Adhanom Ghebreyesus. "I thank and congratulate the governments, health workers, community volunteers, traditional and religious leaders and parents across the region who have worked together to kick wild polio out of Africa."

Strong leadership and innovation were instrumental in stopping the wild poliovirus in the region. Countries successfully coordinated their efforts to overcome major challenges to immunizing children, such as high levels of population movement, conflict and insecurity restricting access to health services, and the virus's ability to spread quickly and travel across borders. In addition, the continued generosity and shared commitment of donors – including governments, the private sector, multilateral institutions and hilanthropic organizations – to achieving a polio-free world helped build the infrastructure that enabled the African region to reach more children than ever before with polio vaccines and defeat wild polio.

"During a challenging year for global health, the certification of the African region as wild poliovirus-free is a sign of hope and progress that shows what can be accomplished through collaboration and perseverance," said Rotary International President Holger Knaack. "Since 1996, when Nelson Mandela joined with Rotary, the Global Polio Eradication Initiative, and governments of the African region we've achieved something remarkable. Today's milestone tells us that polio eradication is possible, as long as the world remains committed to finishing the job. Let us work together to harness our collective energies to overcome the remaining challenges and fulfil our promise of a polio-free world."

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The resources and expertise used to eliminate wild polio have significantly contributed to Africa's public health and outbreak response systems. The polio programme provides far-reaching health benefits to local communities, from supporting the African region's response to COVID-19 to bolstering routine immunization against other vaccine-preventable diseases. While this is a remarkable milestone, we must not become complacent. Continued commitment to strengthening immunization and health systems in the African region is essential to protect progress against wild polio and to tackle the spread of type 2 circulating vaccine-derived poliovirus (cVDPV2), which is present in 16 countries in the region. Pockets of low immunity mean such strains continue to pose a threat and the risk is magnified by interruptions in vaccination due to COVID-19, which have left communities more vulnerable to cVDPV2 outbreaks. The GPEI calls on countries and donors to remain vigilant against all forms of polio. Until every strain is eradicated worldwide, the incredible progress made against polio globally will be at risk. The WHO African Region's success against wild polio has shown the world that progress against some of the biggest global health challenges is possible. The GPEI is grateful for every person, partner, donor and country who helped bring about this incredible achievement.

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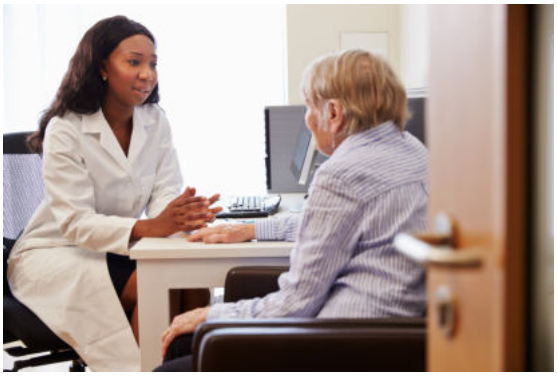
"Partnering with Patients in Asia"

MAPS (Medical Affairs Professional Society (www.medicalaffairs.org), one of IFAPP's strategic partners, held a webinar on "Partnering with Patients in Asia" on 25 August 2020, which was attended by almost 140 people from the healthcare industry in Asia. The webinar focused on patient insights, patient engagement and patient education as important elements of a good medical affairs plan.

Patient insights form a crucial part of the medicine journey from bench to bedside, by supporting organizations to make informed decisions throughout the lifecycle of medicines. In the whole Asian region there is a wide variability in effective implementation and utilization of patient insights across therapeutic segments, organizations and product lifecycle. Integrated patient insights into the drug development continuum from preclinical through clinical research and finally to regulatory approval and launch help to identify barriers along the patient journey that eventually influence patient outcomes.

Patients today are very well informed compared to patients in the past. They want to be more in control. They want ownership of their health. They want flexible and tailored management tools and facilities available to them. They also want to collaborate with players within health systems, including the pharmaceutical industry, academia, and regulators. Within patient communities, we also find advocates and champions who participate in educational publishing and dissemination of data that matter to patients. Patients are looking beyond just efficacy and safety, into overall quality of life not only of the patients, but also of their caregivers. Finally, they are looking for equity and fairness in medicines access. Looking at the patient journey through the lens of a patient allows us to understand and to identify the critical points in partnership with them and address these together, thus increasing access as well as accelerating their journey towards better patient outcomes. Globally and throughout theAsia-Pacific region, there is a need to develop clear guidance and frameworks on effective and systematic patient engagement.

In the webinar, we also learned about why we should move from the box of tissues to the box of medicine, whereby we involve patients as partners in the above areas of insights and engagement. This means we can move from having patients inspire us to having patients transform how we do medicines development in partnership with us. When we look at patient education in the more passive way and perhaps the traditional way we think about patient education in the form of booklets or via a website. However what if we had a partnership with patients for publications and we involved them in publication-planning generation and sharing? This would imply that patients are active in publication-steering committees, involved as authors and contribute to the generation of plain language summaries of publications.



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The Q&A interaction with the attendees led to an insightful and engaging dialogue on this crucial topic, with a clear understanding that much still needs to be accomplished to better incorporate the mindset and involvement ofpatients as partners in medical planning.

Dr.Ajay Tiku, Region Medical Head, Asia Pacific, Middle East and Africa (APMA), Novartis, Singapore

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Dr. Karen Woolley, Global Lead Patient Partnerships, Medical Affairs, Envision Pharma

THE FLAG

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