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The Global Pharmaceutical Medicine Journal

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS AND PHARMACEUTICAL MEDICINE

THIS ISSUE INCLUDES:

The New EU Pharmaceutical Legislation

A regulatory conference on a timely and demanding topic, held in Sofia, Bulgaria, on 4 June 2026, reaffirmed the role of the Bulgarian Association for Drug Information as a platform for expert dialogue.

The regulatory conference in Sofia, organised by the Bulgarian Association for Drug Information (BADI) under the leadership of

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Prof. Tatyana Benisheva, President BADI, brought together more than 95 professionals from regulatory affairs, the pharmaceutical industry, healthcare institutions and academia. The event focused on the ongoing reform of the pharmaceutical legislation of the European Union (EU) and its practical implications for patients, regulators, industry and national healthcare systems.

The main topics discussed included the availability and security of supply of medicinal products, incentives for innovation, the efficiency of regulatory procedures, health technology assessment, antimicrobial resistance, environmental requirements and the growing importance of precision medicine.

Speakers, moderators and organisers of the event from left to right: Dr Momchil Sidgimov and Victor Sidgimov, Prof. Barbara Sickmüller, Prof. Tatyana Benisheva, Assoc. Prof. Lybina Todorova, Dr Birka Lehmann, Prof. Harald Enzmann, Prof. Christa Wirthumer-Hoche, Prof. Dobriana Sidgimova with her family (Momchil and Victor).

The conference examined some of the most significant changes introduced by the new EU framework, including:

- the preservation and further development of incentives related to regulatory data protection, market protection and market exclusivity;
- new incentives for repurposing medicinal products, for the development of priority antimicrobials and for the use of transferable exclusivity vouchers with potentially significant economic value;
- stricter environmental requirements, including environmental risk assessment;
- simplified and more efficient regulatory procedures;
- stronger measures to address antimicrobial resistance;
- new instruments for preventing and managing shortages of medicinal products.

Prof. Christa Wirthumer-Hoche, former Head of the Austrian Agency for Health and Food Safety and former Chair of the Management Board of the European Medicines Agency, presented the new provisions aimed at securing the supply of medicines in Europe, addressing shortages and strengthening the resilience of supply chains.

In her lecture, "Securing Europe's Medicines – New Provisions", she addressed one of the most important questions in contemporary European medicines policy: how Europe can ensure more reliable access to medicines in a context of global manufacturing dependencies, supply-chain disruptions and an increasing risk of shortages.

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A central message of the lecture was that the security of medicine supply can no longer be viewed solely as a logistical or commercial issue. It has become part of regulatory and public health responsibility. The presentation clearly showed that the new EU framework is not based on a single legal act, but on several interconnected instruments: the revised pharmaceutical legislation, the extended mandate of the European Medicines Agency, the Critical Medicines Act and the European Health Data Space. Together, these instruments aim to move the system away from reacting after shortages occur and towards earlier forecasting, prevention and coordination.

Particularly important for the audience was the discussion of the new obligations of marketing authorisation holders. These include earlier notification in cases of market withdrawal or interruption of supply, shortage prevention plans, shortage mitigation plans and a greater responsibility for ensuring continuity of supply.

Speakers and moderators from left to right: Dr Birka Lehmann, Margarita Strokova (BADI Board Member), Rozalina Kulaksasova (BDA, EMA-CAT member), Darina Sooeva (Editor of Forum Medicus Newspaper) Maria Popova (BDA, EMA-PRAC member), Assoc. Prof. Lybina Todorova (BDA, EMA-CHMP member), Prof. Barbara Sickmüller, Prof. Christa Wirthumer-Hoche, Prof. Harald Enzmann, Prof. Tatyana Benisheva, Radoslava Naidenova (Nobelpharma), Lena Gebert (Global Drug Development). At the front on the left: Prof. Dobriana Sidgimova, Daniela Cherneva (Medochemie)

This marks a significant shift in the logic of European medicines policy. Companies are no longer seen only as applicants and holders of marketing authorisations, but also as active participants in maintaining the resilience of healthcare systems. The lecture was especially valuable because it did not present the reform as a guarantee that medicine shortages would disappear.

On the contrary, the message was realistic: the new instruments may make shortages less frequent, more predictable and more manageable, but their success will depend on implementation, coordination between Member States and the willingness of industry to operate in a more transparent and responsible environment.

Prof. Barbara Sickmüller, Chair of the German Association for Regulatory Affairs (DGRA) and expert at the German Federal Association of the Pharmaceutical Industry (BPI), provided an updated and systematic analysis of the impact of the pharmaceutical legislation reform on patients and industry.

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In her lecture, "Current Changes in the EU Pharmaceutical Legislation – Update 2026", Prof. Sickmüller presented the reform not as a formal legislative exercise, but as a new balance between innovation, access to medicines, data protection, market protection, environmental obligations and regulatory efficiency.

She explained the structure of the new legal framework, which preserves the dual system of a directive and a regulation, as well as the dual system of marketing authorisation procedures. She succeeded in presenting this highly complex framework within approximately one hour, which was of particular value to the Bulgarian participants, many of whom work directly with these processes and need to understand where their professional focus should be placed.

At the same time, the new regulation consolidates important elements of the existing regulatory framework, including legislation relating to the centralised procedure, orphan medicinal products and paediatric medicinal products. This is an important aspect of the reform, as it reflects an effort to create greater coherence and a clearer regulatory architecture.

A substantial part of the analysis was devoted to regulatory data protection and market protection. Prof. Sickmüller presented the new approach, under which the basic period of regulatory data protection remains an essential element of the system, while market protection and additional incentives are linked to specific conditions. Particular attention was paid to the possibility of additional protection in cases involving a significant new indication addressing an unmet medical need or clinical trials conducted in the European Union, subject to the limits and conditions set out in the legislation.

Prof. Sickmüller also focused on the concept of unmet medical need, which is directly relevant to future incentives and protection periods. The emphasis was on clinically meaningful improvement in efficacy or safety compared with existing products or therapeutic methods. This is a key change, because it directs incentives not merely towards formal innovation, but towards demonstrable therapeutic value.

The lecture also addressed repurposing, orphan medicinal products, paediatric medicinal products, antimicrobial resistance, transferable exclusivity vouchers and environmental risk assessment. The expert paid particular attention to incentives for priority antimicrobials, including the transferable exclusivity voucher. This mechanism is intended to encourage investment in the development of new antimicrobials in an area where the return on investment has traditionally been low. The voucher may provide an additional period of regulatory protection for a selected product and may, under strict conditions, be transferred to another marketing authorisation holder.

The holder of the voucher may use it for one of its own medicinal products or transfer it to another marketing authorisation holder. Its use is subject to important restrictions, including anti-blockbuster limitations intended to prevent the mechanism from being applied to the highest revenue products and to direct the incentive towards areas of greater public health value.

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The purpose of the transferable exclusivity voucher is to stimulate investment in new antimicrobials, support the fight against antimicrobial resistance and provide an economic incentive in a therapeutic field where conventional market dynamics do not sufficiently reward innovation.

It was also explained that the reform will simplify the structure of the European Medicines Agency's scientific committees for human medicines, leaving the Committee for Medicinal Products for Human Use (CHMP) and the Pharmacovigilance Risk Assessment Committee (PRAC) as the core committees. Other areas of expertise, including paediatric medicines, herbal medicines and advanced therapies, will be reorganised through working parties and expert structures, depending on the specific scientific expertise required.

The analysis of the new requirements for environmental risk assessment was also of considerable practical importance. In particular, the presentation highlighted that an incomplete or insufficiently justified environmental risk assessment may become a ground for refusing a marketing authorisation.

The importance of generic medicinal products was also addressed, although indirectly, as part of the broader discussion on access, sustainability and the balance between innovation and affordability.

This lecture was of high practical value for the participants, as it provided a working framework for understanding the reform: how development strategies will be planned, how incentives will be assessed, how added therapeutic value will be demonstrated and how the new rules will influence market-access strategies.

Dr Birka Lehmann, former member of the Paediatric Committee of the European Medicines Agency, and Chair of IFAPP's Education and Certification Working Group (ECWG), examined regulatory data protection, market exclusivity and the legislative changes affecting paediatric medicinal products and orphan medicinal products. In her lecture, "Regulatory Data Protection, Paediatric Medicinal Products and Orphan Medicinal Products – Changes in the New EU Legislation", Dr Lehmann continued the discussion of the new European framework, but with a more specific focus on regulatory data protection, paediatric medicinal products and medicines for rare diseases. She explained the distinction between the regulation, which governs scientific and administrative aspects, and the directive, which covers marketing authorisation, data protection, market protection and market exclusivity.

A particularly important part of the lecture was the analysis of the changing role of CHMP. Instead of fragmented and sequential procedures, the new framework moves towards more integrated interaction, in which paediatric and orphan aspects are considered earlier and more systematically throughout the lifecycle of the product. The practical value of the presentation lay in showing that companies will need to plan paediatric obligations and orphan strategies from the early stages of development.

The lecture also presented data showing that only a proportion of products receiving orphan designation ultimately reach marketing authorisation. The discussion then turned to the Bulgarian context, where access to orphan medicinal products remains a serious practical and ethical issue. Even when products are authorised at European level, their actual availability for patients in Bulgaria may be limited by pricing, reimbursement and market-access constraints. This raises important ethical questions, as many patients cannot finance such therapies themselves, while some products do not reach the national market in a timely and sustainable manner.

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Mag. pharm. Lena Gebert, former expert at the Paul-Ehrlich-Institut and European Medicines Agency assessor in the field of biological and biosimilar medicinal products, presented regulatory decision-making and comparability assessment for monoclonal antibodies after changes in the manufacturing process.

In her lecture, "Regulatory Decision-Making in the Assessment of Comparability of Monoclonal Antibodies after Manufacturing Process Changes", Lena Gebert examined comparability assessments for monoclonal antibodies following manufacturing changes. The topic is particularly important for biological medicinal products, where the manufacturing process is inseparable from the characteristics of the product itself.

The presentation demonstrated that, where analytical and functional comparability has been properly established, regulatory decisions can be scientifically justified without automatically requiring new clinical trials. The analysis covered 39 manufacturing changes. In 24 cases, no quality differences were identified, while in 15 cases differences were detected and assessed individually according to their regulatory relevance.

The main value of the lecture was the practical distinction it made between different types of evidence: analytical data, in vitro functional tests, mechanistic studies, historical clinical data and pharmacological traceability for biological medicinal products. This gave participants a clear view of how "quality drift" is assessed in a real regulatory environment.

Prof. Ilko Getov, Chair of the National (Bulgarian) Council on Prices and Reimbursement of Medicinal Products (NCPRMP), together with **Boryana Ivanova**, expert in Health Technology Assessment (HTA) at the Council, presented the first joint clinical assessments under the new European HTA framework and their impact on access to innovative therapies.

In their joint lecture, "First Joint Clinical Assessment under HTAR – The Role of NCPRMP in the EU Joint HTA Work", Prof. Getov and Ms Ivanova presented the HTA Regulation (HTAR) in a direct national and practical context. They explained the first joint clinical assessment under Regulation (EU) 2021/2282 and the role of the National Council on Prices and Reimbursement of Medicinal Products in the European HTA process.

The presentation focused on the core principles of joint clinical assessments: common scientific and clinical aspects, quality and timeliness of reports, transparency, stakeholder involvement and a stepwise approach. Particular attention was paid to the link between the European assessment and the national HTA process, including the preparation of the Population Intervention Comparator Outcome (PICO), the use of the HTA IT platform and the subsequent application of Joint Clinical Assessment (JCA) reports in national decision-making.

The practical value of the lecture was that it showed how the European HTA framework will affect the work of companies and institutions in Bulgaria. HTAR was not presented as a distant administrative reform, but as a real process that will change dossier preparation, interaction with institutions and market-access planning. At the same time, it was clearly underlined that reimbursement remains a national procedure. Each Member State will continue to decide which therapies it will pay for, irrespective of a positive European HTA assessment.

Prof. Harald Enzmann, former Chair of the CHMP at the European Medicines Agency, delivered a lecture on the role of biomarkers in precision medicine and the future of targeted therapies.

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In his lecture, "Biomarkers as Prerequisite for Accurately Targeted Precision Medicines", Prof. Enzmann examined biomarkers as a foundation of precision medicine and as a prerequisite for defining the appropriate target patient population. The topic was presented not only as a scientific issue, but also as a regulatory and practical factor in the authorisation and use of medicinal products.

The lecture also outlined future regulatory questions linked to increasingly small target populations, real-world data and the need for marketing authorisations to adapt to new evidence over time.

The moderators of the discussions, Prof. Tatyana Benisheva, Ekaterina Genova, Daniela Cherneva, Margarita Strokova and Radoslava Naydenova, contributed significantly to the clear structure of the event and to the professional conduct of the discussions. Their role was important because the programme covered complex topics requiring a bridge between the European legislative perspective and the specific practical questions facing the Bulgarian pharmaceutical environment. The discussions helped clarify how these new rules and processes may operate in practice in Bulgaria, which was one of the central objectives of the conference.

Under the leadership and organisation of Prof. Tatyana Benisheva, the conference provided valuable proactive knowledge and practical guidance on the development of the European regulatory environment. It also underlined the importance of cooperation between regulators, the pharmaceutical industry, healthcare professionals, academia and policy-makers in ensuring patient access to safe, effective and innovative medicinal products.

In conclusion, the BADI Regulatory Conference 2026 was an event of high expert value and clear practical relevance. The lectures of Prof. Christa Wirthumer-Hoche and Prof. Barbara Sickmüller provided a strong strategic and legislative foundation for understanding the European pharmaceutical reform over the coming years. The other presentations built upon this framework with specific regulatory and scientific analyses of paediatric and orphan medicinal products, biological medicinal products, health technology assessment and biomarkers.

With the participation of approximately 95 professionals from regulatory institutions, the Bulgarian Drug Agency, the NCPRMP, academia and industry, the conference reaffirmed the role of BADI as a distinctive platform for expert dialogue, professional training and knowledge exchange in the field of medicines regulation in Bulgaria.

Equally important, the event provided current and practically applicable information on the changes that will shape the European pharmaceutical environment in the years ahead.

After the event, participants enjoyed a two-day social programme during which the speakers and moderators visited the historic Bulgarian villages of Etara and Bozhentsi. Both are well-preserved heritage sites. Etara is an open-air ethnographic museum showcasing traditional Bulgarian crafts and architecture, while Bozhentsi is not only a museum village but also a living community where people continue to reside.

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Etara

Bogenzi - From left to right: Prof. Dobriana Sidgimova, Margarita Strokova, Prof. Harald Enzmann, Prof. Tatyana Benisheva, Prof. Christa Wirthumer-Hoche, Dr Birka Lehmann

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MEAPP Contributes to Africa Health ExCon 2026 by Advancing Dialogue on Clinical Research and Liver Disease

The Middle East Association of Pharmaceutical Medicine Professionals (MEAPP) was pleased to contribute to the scientific programme of **Africa Health ExCon 2026**, held in Cairo, Egypt, from 15-19 June 2026 for the second year in a row.

Held annually in Egypt, under the patronage of H.E. President Abdel Fattah El-Sisi and co-hosted by Africa Centres for Disease Control and Prevention (Africa CDC) in collaboration with the Egyptian Authority for Unified Procurement (UPA), Africa Health ExCon is the continent's only institutional healthcare exhibition combining government procurement access, ministerial participation, and international B2B trade under one roof. This year's edition attracted more than 45,000 participants, featured over 400 exhibitors, and delivered a comprehensive scientific programme covering healthcare innovation, regulatory harmonisation, digital transformation and capacity building.

In collaboration with the Society of Liver Disease in Africa (SOLDA), MEAPP led a high-profile session entitled **"Accelerating Hope for Liver Disease Patients in Africa: Early Access, Unmet Needs, and Clinical Research Barriers."**

The session commenced with a keynote presentation by **Dr Assem el Baghdady**, MD, FFPM, FRCP, Founder and President of MEAPP and Senior Lecturer in Pharmaceutical Medicine at King's College London, who highlighted Africa's growing burden of liver disease alongside the continent's significant opportunities to become a global contributor to clinical research and medicines development. He emphasised the importance of regulatory strengthening, research infrastructure, capacity building and multi-stakeholder collaboration in accelerating access to innovative therapies for African patients.

Dr Assem el Baghdady delivering the keynote presentation, "Accelerating Hope for Liver Disease Patients in Africa: Early Access, Unmet Needs, and Clinical Research Barriers," at Africa Health ExCon 2026

The panel discussion brought together experts from academia, government, regulatory authorities, CDC, and clinical research institutions to explore the challenges and opportunities for advancing clinical research in Africa.

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Panelists from right to left

- **Dr Elvis Temfack** – Head of the Division of Research & Development and Clinical Trials Coordination, Africa CDC
- **Prof. Wendy Spearman** – Professor of Hepatology, University of Cape Town and Vice President of SOLDA
- **Hon. Prof. Manal Hamdy El-Sayed** – Member of the Egyptian House of Representatives, Professor of Paediatrics, former Director of the Clinical Research Centre at Ain Shams University and President of SOLDA
- **Senator Prof. Sherif Wadie** – Head of the Supreme Council for the Review of Clinical Medical Research Ethics, Egypt, and Adviser to the Minister of Health.
- **Prof. Fatma Ebeid** – Professor of Hematology, Oncology and Bone Marrow Transplant and Director of MASRI Clinical Research Centre, Ain Shams University
- **Dr George Maher** – Chief Executive Officer, MARC Research Centre
- **Dr Assem el Baghdady:** Founder and President of MEAPP and Senior Lecturer in Pharmaceutical Medicine at King's College London

Panel Moderator:

- **Dr Yasmin Nagaty:** Regional Manager at MEAPP and Visiting Lecturer at King's College London

Addressing Africa's Clinical Research Challenges

The panel explored the barriers that continue to limit timely access to innovative therapies for liver disease patients across Africa. Despite carrying a disproportionate share of the global liver disease burden, many African countries remain underrepresented in international clinical trials and experience delayed access to innovative medicines.

Key themes discussed included:

- Persistent misconceptions among global sponsors regarding Africa as a destination for high-quality clinical research.
- Opportunities to strengthen regulatory harmonisation and streamline clinical trial approval processes.
- The critical role of Africa CDC, national regulatory authorities and ethics committees in fostering regional collaboration.
- The importance of developing sustainable clinical research infrastructure across the continent.

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- Investment in human capital through training investigators, regulatory assessors and pharmaceutical medicine professionals.
- Building strategic partnerships between academia, regulators, industry and healthcare institutions to accelerate innovation and patient access.

Capacity Building at the Heart of MEAPP's Mission

A recurring message throughout the session was that infrastructure and regulatory reform alone are insufficient without investment in people.

Reflecting MEAPP's long-standing commitment to education and professional development, Dr el Baghdady highlighted the importance of strengthening the African clinical research workforce by training investigators, pharmaceutical physicians, regulatory professionals and clinical research practitioners. Such investment is fundamental to improving research quality, attracting international clinical studies and ultimately ensuring equitable access to innovative therapies across Africa.

Looking Ahead

The session concluded with a clear call for stronger collaboration across the healthcare and research ecosystem. Bringing together policymakers, regulators, academia, industry and public health organisations demonstrated how multidisciplinary dialogue can translate into practical actions that improve research capacity and patient outcomes.

MEAPP is proud to have contributed to this important conversation and remains committed to supporting clinical research excellence, regulatory science, education and capacity building throughout the Middle East and Africa. The Association extends its sincere appreciation to SOLDA for its valued collaboration in organising this session, as well as to Africa Health ExCon, the distinguished panelists and the engaged audience for making the discussion both impactful and inspiring.

Together, these partnerships are helping to accelerate equitable access to innovative therapies and build a stronger clinical research ecosystem for patients across Africa.

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Planting Seeds of Science: How a TWAS Grant Programme Is Reshaping African Research and Why IFAPP Should Take Notice

Somewhere in Zimbabwe, a young researcher is investigating how perinatally acquired HIV may accelerate brain ageing, seeking affordable biomarkers that could transform neurological care in resource-limited settings. Another early career scientist is exploring shared immune mechanisms underlying HIV-associated cardiac and neurological disease. In Ghana, an early-career investigator is combining traditional medicinal knowledge with modern molecular biology to uncover new therapeutic pathways for Alzheimer's disease. All three received something that, in the life of a scientist working in a resource-constrained institution, can be genuinely transformative: a Seed Grant for New African Principal Investigators, known by its acronym, SG-NAPI.

I have had the privilege of serving as a reviewer for this programme for the past four years. What I have witnessed in that role - the steady rise in scientific rigour, the breadth of intellectual ambition, genuine gender parity among applicants, and research with direct implications for healthcare policy - is precisely why I am bringing this initiative to the attention of the IFAPP community today.

What Is SG-NAPI?

Launched in 2020 by UNESCO*-TWAS (The World Academy of Sciences) and fully funded by the German Federal Ministry of Research, Technology and Space (BMFTR), the SG-NAPI programme addresses one of the most persistent structural challenges in global science: brain drain. It targets a critically underserved group of early-career African scientists aged 40 years or younger who have earned their doctorate abroad and have returned, or committed to return, to an academic or research institution in their home country. The programme is built on a simple but powerful principle: give talented scientists a reason to stay, together with the resources to conduct outstanding research.

Grants of up to US$ 67,700 are awarded for a period of 30 months and may be used for scientific equipment, consumables, MSc student support, open-access publication costs, conference participation, and collaborative mobility with German research partners. A particularly forward-thinking component, the Scientist-after-Child Grant, specifically supports female researchers returning from maternity leave. Since its first call in 2021, the programme has funded 58 grants across two funding cycles and, in November 2024, brought together 62 grantees from 20 African countries for a landmark Skills-Building Workshop in Dakar, Senegal.

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The 2026 call is now aligned with Germany's High-Tech Agenda, opening new opportunities in artificial intelligence, biotechnology, and quantum technologies.

SCIENTIST-AFTER-CHILD

A unique component designed to support early career female scientists during and/or after pregnancy. The component allows the scientist to recruit a research assistant for up to 12 months so she can spend time with her new born or infant.

Featured on the left is **Dr. Rosemary Bulyaba**, from Uganda, a 2021 grant recipient.

"Receiving the SG-NAPI was a huge help for my scientific career. **I could continue my research with the aid of an assistant while staying at home and breastfeeding,**".
"This grant has **strengthened my reputation and increased my value** at Uganda Christian University. My career was uplifted: I was head of the department and **now I am the Dean of the Faculty of Agricultural Sciences.**"

What I See as a Reviewer

When I first joined the review panel, I brought the clinical and regulatory perspective developed over more than a decade of advising on drug development strategy across medicines, medical devices, and in vitro diagnostics. What I did not fully anticipate was the calibre of science I would encounter.

Over the years, the quality of applications has risen markedly. Proposals are increasingly well structured, hypothesis driven and, crucially, attuned to health policy implications and translational relevance. This is no longer a purely academic exercise; these researchers understand that their work must generate evidence capable of informing healthcare systems. I have also been struck by the genuine gender balance among applicants. The programme actively encourages women scientists, and the applications reflect a parity that feels earned rather than mandated.

This year, I reviewed four applications from Cameroon, Zimbabwe, Ghana, and South Africa, all within the fields of Biology and Medical Sciences. HIV, its impact through perinatal transmission, and the long-term immunological and neurological consequences for children growing up with the infection continue to dominate this landscape, and rightly so. Sub-Saharan Africa carries a disproportionate share of the global HIV burden, and researchers working within this context bring an invaluable perspective and insight. Equally striking this year, however, was the emergence of metabolic disease as a major research priority. Type 2 diabetes, cardiovascular disease, and obesity-related comorbidities are increasing rapidly across the continent, and African researchers are not waiting for the global health community to shift its focus. They are already leading the way by designing high-quality studies, asking clinically relevant questions, and generating the evidence that will help shape the next generation of African clinical guidelines.

The People behind the Programme

SG-NAPI does not succeed through institutional momentum alone. Max Paoli, Programme Coordinator at TWAS, approaches science funding as a moral commitment. His dedication to Africa's scientific future is reflected in every aspect of the programme, from the trilateral grant agreement that brings together principal investigators, their institutions and TWAS in shared accountability, to the deliberate investment in the next generation of MSc students supported by each grant.

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"There is a reason why this joint programme focuses on capacity building and younger generations. They are our future and need training and new skills to build better societies." Max Paoli, Programme Coordinator, TWAS.

Equally indispensable is Memoth Kanniakonil (kanniakonil@twas.org) whose operational precision and personal commitment ensure that applicants, often working under significant infrastructure constraints, receive the guidance needed to submit proposals of the highest possible quality.

"Every application we receive represents a researcher who chose to come home. Our role is to make sure that choice is rewarded with the tools needed to do meaningful science." Memoth Kanniakonil, TWAS SG-NAPI Grants Office.

The human impact of this programme is best illustrated through the stories of its grantees. Cornelia Appiah-Kwarteng as mentioned on the TWAS website (https://twas.org/article/returning-africa-make-difference), a parasitologist who completed her PhD in Japan before returning to the University of Ghana, used her SG-NAPI grant to establish molecular biology infrastructure that now supports her entire department, not only her own laboratory. Yannick Nuapia, from the Democratic Republic of Congo, is a pharmacist and toxicologist trained at the University of the Witwatersrand, South Africa. His research focuses on the bioactive properties of Moringa oleifera, while he also advises the Ministry of Health of the Democratic Republic of the Congo on pesticide and heavy metal contamination in the food supply. Both exemplify applied scientists in the truest sense, translating laboratory research into tangible benefits for healthcare and public policy.

Why this Matters for IFAPP

IFAPP is dedicated to advancing the research underpinning the development of medicines worldwide. SG-NAPI represents a natural and timely alignment with that mission. Its grants can contribute to strengthening pharmaceutical capacity in Africa, where only around 3% of the medicines consumed are currently produced locally. Supporting the next generation of African researchers is therefore not only an investment in research and science, but also in the continent's long-term ability to develop and manufacture medicines for its own populations.

The researchers emerging from this programme will design clinical studies, generate epidemiological data on the burden of disease in Africa, strengthen pharmacovigilance infrastructure, and build the regulatory science capacity on which Pharmaceutical Medicine across the continent will depend for decades to come. Drug development that overlooks African populations, their disease profiles, genetic diversity, and healthcare systems, ultimately results in medicines that are less safe and less effective for a substantial proportion of the world's population.

As pharmaceutical physicians, clinical pharmacologists, and drug development professionals, we possess expertise in clinical trial methodology, benefit-risk assessment, patient stratification, and regulatory strategy that could make a meaningful contribution to these early-career scientists. Whether as peer reviewers, scientific mentors, or research collaborators, the IFAPP community has much to offer and, arguably, just as much to learn.

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Africa's disease landscape is not a regional footnote to global medicine. It is a defining part of it, and it is being studied with growing sophistication and increasing confidence by scientists who understand it from within. SG-NAPI is helping to make this possible. It deserves our attention, our professional engagement, and our partnership.

Reference: *UNESCO: the United Nations Educational, Scientific and Cultural Organization

Author: Ghazaleh Gouya-Lechner, MD, Founder & CEO, Gouya Insights; Board Member GPMed and IFAPP

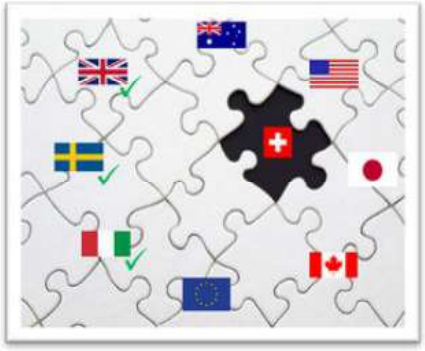
Pull Incentives for Antibiotics are Gaining Momentum

The June 2026 newsletter of the Swiss Round Table on Antibiotics (RTA) highlights initiatives in Switzerland aimed at supporting the revival of the global antibiotics market while improving the country's prospects of attracting the registration of new antibiotics despite its small market size.

However, Switzerland cannot succeed in isolation. The comprehensive overview of international approaches to the design, planning, and implementation of pull incentives - shared and discussed at a meeting in Brussels by leading experts on pull incentives - provided timely and highly valuable support.

You can find the Swiss RTA June newsletter here: Swiss Round Table on Antibiotics | News

The green ✓ marks the countries that have already implemented pull incentives into practice.



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A Joint Statement towards the Highest Ethical Standards for Health Databases and Biobanks discussed at an IFAPP Webinar Focusing on Indigenous Peoples, Vulnerable Patients, and the Global South

The IFAPP Webinar held on 25 May 2026 (1) has addressed the World Medical Association's (WMA) Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks (2), which is currently under revision by the WMA. Following three hours of extensive debate, to bring underrepresented voices to the forefront, we, the presenters and organisers, advocates for Indigenous peoples, vulnerable patients, and communities in the Global South, have compiled this Joint Statement. This Statement was widely circulated via the link below among interested parties including the WMA, just before the WMA's meeting in Rome, on 1 and 2 June 2026 (3), and finalised just afterwards. You can find the videorecording of the webinar and presentations of all the speakers here: https://drive.google.com/drive/folders/1ZhwYpgARhzLCUb3PbQNPXZTfa6BanQTr

1. Why are the genetic and genomic data of Indigenous peoples particularly important?

- **The Universal Value of Heritage:** The genetic and cultural heritage of Indigenous peoples holds immense scientific, social, and anthropological value. Their rights to dignity, integrity, autonomy, and freedom to choose must always be respected.
- **Global Public Goods:** These genetic and genomic characteristics, passed down through millennia, are a profound source of identity and pride. While they offer invaluable insights for global health, the derived knowledge constitutes a common heritage of humanity and must be managed as "public goods".

2. What is actually happening?

- **Biopiracy and Biocolonialism:** A systemic imbalance persists between industrialised nations and economically marginalised Indigenous peoples. While their biological samples are frequently collected, the benefits are rarely shared equitably. This predatory extraction reflects ongoing practices of biopiracy and biocolonialism.
- **The Representation Gap:** There is a profound contradiction: although genetic studies are frequently conducted on Indigenous peoples, their data remain severely underrepresented in large-scale cohort databases. This discrepancy stems from historic mistrust, a lack of culturally sensitive engagement, and practical logistical barriers, effectively excluding vulnerable populations from global health benchmarks, even though their genetic sequence data demonstrate their significant contribution to the evolution of human health.
- **Challenges in Free, Prior, and Informed Consent (FPIC) *(4,5):** During the collection of samples and data it becomes increasingly difficult for individuals not only to fully understand the proposals but, more importantly, to agree with many of the potential negative impacts on their well-being, such as:

  (2.1) Genetic Implications: The long-term and highly complex consequences of genetic analysis.

  (2.2) Indefinite Use: The proposal for broad, multiple, indefinite, and hidden uses of data and samples for unspecified purposes in biobanks.

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(2.3) Artificial Intelligence (AI) and Privacy Risks: Unprecedented information risks, the impossibility of complete anonymisation particularly relevant for Indigenous peoples because in many genetic analysis, the data is analysed as a group, hence there cannot be complete anonymity with respect to the community, and the lack of a "right to be forgotten" in AI systems.

(2.4) Community Impacts: Collective risks to whole communities, including stigmatisation, discrimination, and socio-economic exploitation.

(2.5) Geopolitical Risks: The alarming potential for human data to be weaponised for dual-use military applications.

3. What are the most essential actions?

- Active and Meaningful Community Engagement: Participants and their communities have the right to be actively engaged at every stage, including the establishment, cultural governance, and management of health databases and biobanks. This engagement must extend to ethical reviews, information dissemination, and the implementation of results. This approach aligns entirely with the latest 2024 revisions of the WMA Declaration of Helsinki (6).
- Governance of Collective and Dynamic FPIC: Both collective FPIC and individual consent must be continuous and culturally appropriate processes, rather than single administrative acts. Together, they must ensure both communities and individuals understand the long-term impacts of biomolecular data analysis (omic sequencing), biobank storage, and AI risks like losing the right to be forgotten. Crucially, FPIC is a required layer before individual consultation, never a substitute for it. Furthermore, a dynamic consent model must enable both communities and individuals to track data and exercise veto or revocation rights against future research that conflicts with their values, worldviews, or security.
- Structured Benefit-Sharing Plans: Concrete plans to operationalise benefit-sharing must be established in accordance with the International Labour Organization Indigenous and Tribal Peoples Convention (1989) (4), UNESCO Declaration on Bioethics and Human Rights (2005) (7), and the UN Declaration of Rights of Indigenous Peoples (2007) (5). This requires building mutual trust and respect to guarantee post-research access, fostering partnerships including discovery and exploratory phases, and promoting knowledge exchange. This approach is also in alignment with the global move towards UNESCO's principles of open science (8). Strategies regarding Material Transfer Agreements (MTAs), ownership and/or custodianship, intellectual property and heritage rights, and the return of results (RoR) built on a platform of dynamic, iterative consent and community engagements must be clearly defined to ensure equitable outcomes. It is also necessary to establish partnerships and capacity building through academic training to develop strategies for the protection and conservation of genetic heritage. Global norms must be established to apply the "access and benefit-sharing" (ABS) provisions of the Nagoya Protocol (9), to human-derived resources, and emphasising the deficiency that this Protocol currently excludes human genetic resources (HGR).
- Science as a Global Public Good: Scientific outcomes, including genomic analysis and AI-driven innovations, must be managed strictly as "global public goods" and with the effective participation of Indigenous peoples. These technologies must be consolidated to advance solidarity, global justice, peace, and the Sustainable Development Goals (SDGs) (10). They must never be instrumentalised for power politics, used to wage wars, or exploited to reinforce the unequal distribution of wealth. Global norms that prohibit appropriations for intentions and applications (including commercialisation of human-derived samples) not agreed upon and go against the values, ethics, and policies of resource dondrs (vs originators). These human-derived samples and data must always be treated with respect, dignity, and integrity.

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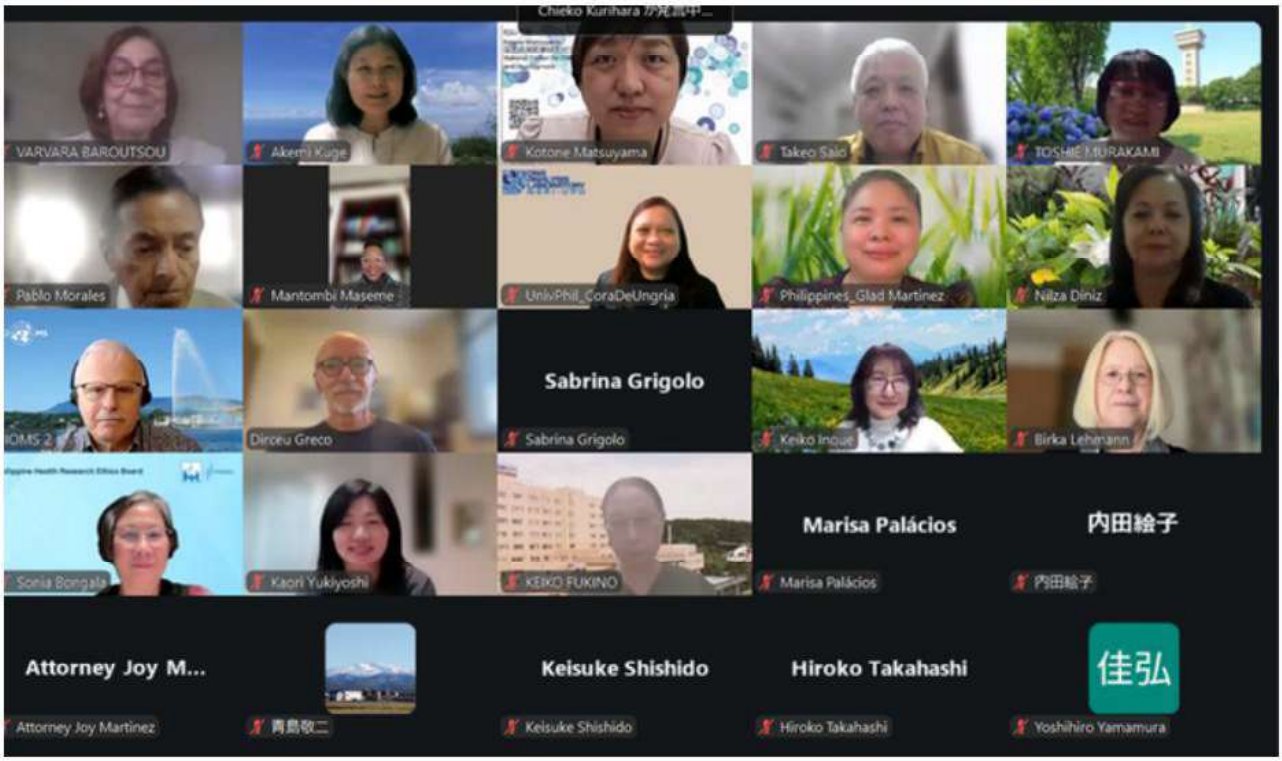
Conclusion: Universal application of this statement

The ethical principles, protections, and rights derived from safeguarding Indigenous peoples apply universally. They extend to all vulnerable patients, research participants, individuals, and communities, recognising that anyone can become vulnerable at any time.

Note:

** Article 31 1 of the United Nations Declaration of Rights of Indigenous Peoples (UNDRIP): Indigenous peoples have the right to maintain, control, protect, and develop their cultural heritage, traditional knowledge, and traditional cultural expressions, as well as the manifestations of their sciences, technologies, and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports, and traditional games and visual and performing arts. They also have the right to maintain, control, protect, and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions."*



Speakers, organisers, and participants of the 25 May 2026 Webinar. It is worth noting that Dr Lembit Rago, Secretary-General of CIOMS, (third from the top in the left-hand column) participated and offered words of encouragement regarding efforts to tackle these challenging issues. On 18 May 2026, one week prior to this webinar, a meeting was held between Dr Rago, Prof. Dominique Sprumont (Vice President of CIOMS and a speaker at the WMA's meeting on the DoT in Rome, 1 and 2 June 2026), and the organisers of the GREEN Statement. The ambitious vision of the GREEN Statement and the discussion on the risks and benefits associated with the development and use of AI were directly incorporated into the discussions during this webinar.

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4. *International Labour Organization. C169 - Indigenous and Tribal Peoples Convention, 1989 (No. 169).*
5. *The United Nations Declaration of Rights of Indigenous Peoples (UNDRIP).*
6. *The World Medical Association. WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants. First adopted in 1964, last amended in 2024.*
7. *United Nations Educational, Scientific and Cultural Organization. Universal Declaration on Bioethics and Human Rights. 19 Oct 2005*.
8. *United Nations Educational, Scientific and Cultural Organization. UNESCO Recommendation on Open Science. 2021. SC-PCB-SPP/2021/OS/UROS*.
9. *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity. October 29, 2010*.
10. *United Nations. Resolution adopted by the General Assembly on 25 September 2015 - Transforming our world: the 2030 Agenda for Sustainable Development. 21 October 2015*.

Webinar Presenters

Keiko Inoue, Akemi Kuge, Toshie Murakami, Eiko Uchida, Yoshiko Saito, Atsushi Yamasaki, Bioethics Working Group, Ji4pe, Japan

Gladness Henna A. Martinez, Philippine Medical Association

Maria Corazon A. De Ungria, Head, DNA Analysis Laboratory, Natural Sciences Research Institute, University of the Philippines Diliman

Liliana Virginia Siede, Professor and Researcher, University of the Argentine National Social Museum

Pablo Morales Males, Director of the Human Health Evolution Project in Ecuador and America,CEO of the Interscientific American Institute for Human Genomics (IABYAGEH)

Mantombi Maseme, Extraordinary Lecturer, School of Health Systems and Public Health (SHSPH), University of Pretoria Pretoria, South Africa

GREEN Statement Organisers

Varvara Baroutsou, Immediate Past President of IFAPP, Greece

Dirceu Greco, Professor Emeritus of Infectious Diseases and Bioethics at the School of Medicine, Federal University of Minas Gerais, Brazil

Kotone Matsuyama, National Center for Child Health and Development; President-Elect, IFAPP, Japan

Takeo Saio, Chieko Kurihara, Clinical Evaluation, Japan

Collaborators

Marisa Palacios, Nilza Maria Diniz, Brazilian Society of Bioethics, Brazil

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Webinar organiser
IFAPP

Supporting organisations
Philippine Medical Association (PMA)
Philippine College of Pharmaceutical Medicine (PCPM)
Japanese Association of Pharmaceutical Medicine (JAPhMed)
Japanese Institute for Public Engagement (Ji4pe)
Brazilian Society of Bioethics (SBB)
Medical Biorepositories of South Africa (MBiRSA)

Authors:
Keiko Inoue, Akemi Kuge, Toshie Murakami, Eiko Uchida, Yoshiko Saito, Atsushi Yamasaki, Gladness Henna A. Martinez, Maria Corazon A. De Ungria, Liliana Virginia Siede, Pablo Morales Males, Mantombi Maseme, Varvara Baroutsou, Dirceu Greco, Kotone Matsuyama, Takeo Saio, Chieko Kurihara, Marisa Palacios, Nilza Maria Diniz (The authors' affiliations are listed above.)

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FROM THE IFAPP COMMUNICATION WORKING GROUP

IFAPP Pharmaceutical Medicine

Congratulations!

WELL DONE, FRANCESCO!

We are delighted to congratulate our IFAPP Communication Working Group member

FRANCESCO BUTTI

on his election as Secretary of SIMeF (the Italian National Member Association of IFAPP) on **May 18th, 2026.**

> *"I'm honored to have been elected by the SIMeF Board as Secretary on **May 18th, 2026**.*
>
> *My experience as a SIMeF delegate at IFAPP has been fantastic, and I'm thrilled to be handing over the role to **Marisa LeDonne**, who received the appointment with the unanimous endorsement of the SIMeF Board."*

A NEW CHAPTER

We warmly welcome and congratulate

MARISA LEDONNE

as the new SIMeF delegate to IFAPP.

Your leadership, dedication and commitment continue to inspire the Pharmaceutical Medicine community.

Wishing you both continued success in your new journeys!

With warm regards,
The IFAPP Communication Working Group

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Key Takeaways from Grow with the Experts June Webinar: Level Up Your Career – The Mentorship Advantage

On 19 June 2026, the IFAPP Young Professionals Working Group (YPWG) hosted another session of the "Grow with the Experts" webinar series, "Level Up Your Career: The Mentorship Advantage." Moderated by Kateryna Uspenska, Chair of the IFAPP YPWG, the webinar featured Francesco Butti, Head of Clinical Development Operations at Boehringer Ingelheim Italy, and Member of the SIMeF (1) Advisory Board, and Marisa Le Donne, Clinical Trial Manager at Boehringer Ingelheim Italy, and Coordinator of the SIMeF Young Professionals Working Group. Drawing on their own experiences as both mentors and mentees, they shared practical advice on how mentoring can accelerate career growth and help professionals navigate their careers with greater confidence.

Rather than focusing on theory, the discussion centred on actionable strategies that professionals at every career stage can apply immediately.

Don't wait for the perfect moment! There is no "right" time to find a mentor. You do not need to have a promotion on the horizon or a major career decision ahead. The professionals who grow the fastest are often those who actively seek advice, ask thoughtful questions, and learn from the experiences of others long before they face their biggest challenges.

Successful mentoring begins with an engaged mentee. Come prepared to each meeting with questions, updates, and topics for discussion. Reflect on previous conversations and follow through on agreed actions. A mentor can provide guidance and perspective, but your professional development ultimately depends on your own commitment and initiative.

Seek guidance, not ready-made answers

A common misconception is that mentors provide solutions to every challenge. In reality, the best mentors ask insightful questions, share their experiences, and encourage critical thinking. Their role is to help mentees develop the confidence and skills to make informed decisions independently.

Be open to constructive feedback

Honest feedback is one of the greatest values of a mentoring relationship. While it can sometimes be uncomfortable, it helps uncover blind spots, challenge limiting assumptions, and accelerate personal and professional growth. Approaching feedback with curiosity rather than defensiveness allows every conversation to become a learning opportunity.

Look beyond your own organisation

Finding a mentor within your own company can be incredibly valuable, but it is not always the easiest option. Many young professionals hesitate to discuss career ambitions, uncertainties, or workplace challenges with someone who may also influence performance evaluations or promotion decisions. While internal mentoring programmes can be highly effective, it is equally important to remember that mentors can be found outside your organisation. Professional associations such as IFAPP, networking events, and cross-company mentoring initiatives offer opportunities to connect with experienced professionals in a safe and supportive environment, where open and honest conversations can flourish.

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Remember that mentoring is a two-way relationship

Mentoring is not only beneficial for the mentee. Mentors also gain new perspectives, learn from different experiences, and stay connected with the challenges faced by the next generation of professionals. The most successful mentoring relationships are built on mutual respect, openness, and continuous learning.

Whether you are looking for your first mentor or considering becoming one yourself, mentorship starts with curiosity, intentionality, and a willingness to grow.

One step to take Today: Start with three questions

One of the most practical recommendations was also the simplest: before searching for a mentor, take a blank sheet of paper and write down the three questions you genuinely want answered. These questions might relate to career progression, leadership, transitioning into a new role, or overcoming a professional challenge. Starting with clear objectives makes it much easier to identify the right mentor and ensures that every conversation has purpose.

Your career is too important to navigate alone. Find someone who challenges you, believes in your potential, and encourages you to become the professional you aspire to be. One conversation today could shape opportunities you never imagined tomorrow.

Reference:

1) SIMeF: Società Italiana di Medicina Farmaceutica (https://www.simef.it)

Author:

Kateryna Uspenska, PhD, Chair of YPWG IFAPP, Senior Clinical Project Manager, Gouya Insights, Vienna, Austria

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Summary of the webinar of 09 July 2026

Mentorship in Pharmaceutical Medicine
The SIMeF Experience in Italy

Speakers:

Marisa Le Donne PharmD PhD
Clinical Trial Manager Cardio-Renal-Metabolism
Boehringer Ingelheim

Tiziana Musacchio PharmD PhD
International Medical Affairs Director
Neuroscience Parkinson's Disease
ABBIVIE

Marisa Le Donne started the webinar by setting the frame:

She continued

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Why SIMeF Launched a Mentorship Program

Addressing the needs of Pharmaceutical Medicine professionals
Facilitate career orientation and professional growth
Connect experienced professionals with younger generations
Promote knowledge-sharing across different functions and career stages
Support the development of both technical and soft skills
Strengthen the Pharmaceutical Medicine community

Program philosophy
A people-centered initiative built around:
Individual goals
Professional aspirations
Personalized mentor–mentee matching

5

... and pointed out the

Benefits for Mentees and Mentors

Mentees
✓ Safe environment for development
✓ Faster professional growth
✓ Increased self-awareness
✓ Better decision-making
✓ Expanded professional network
✓ Greater confidence

Mentors
✓ Reflect on personal experiences
✓ Continuous learning through dialogue
✓ Contribution to future generations
✓ Professional recognition
✓ Networking opportunities
✓ Personal fulfillment

A mutually enriching relationship

6

...and described the practicalities:

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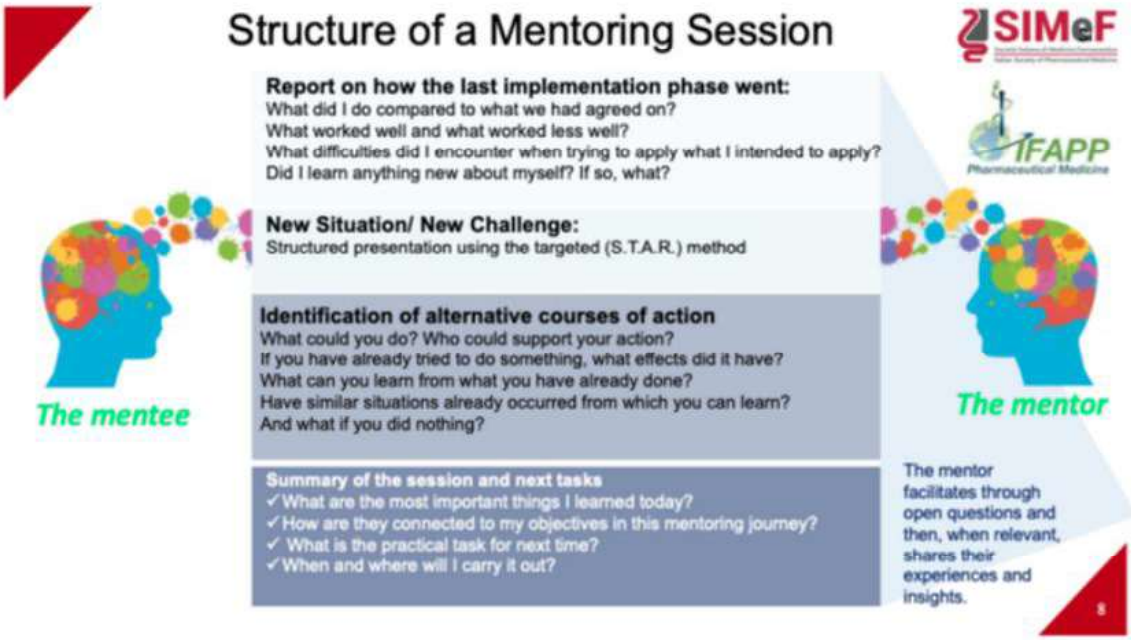
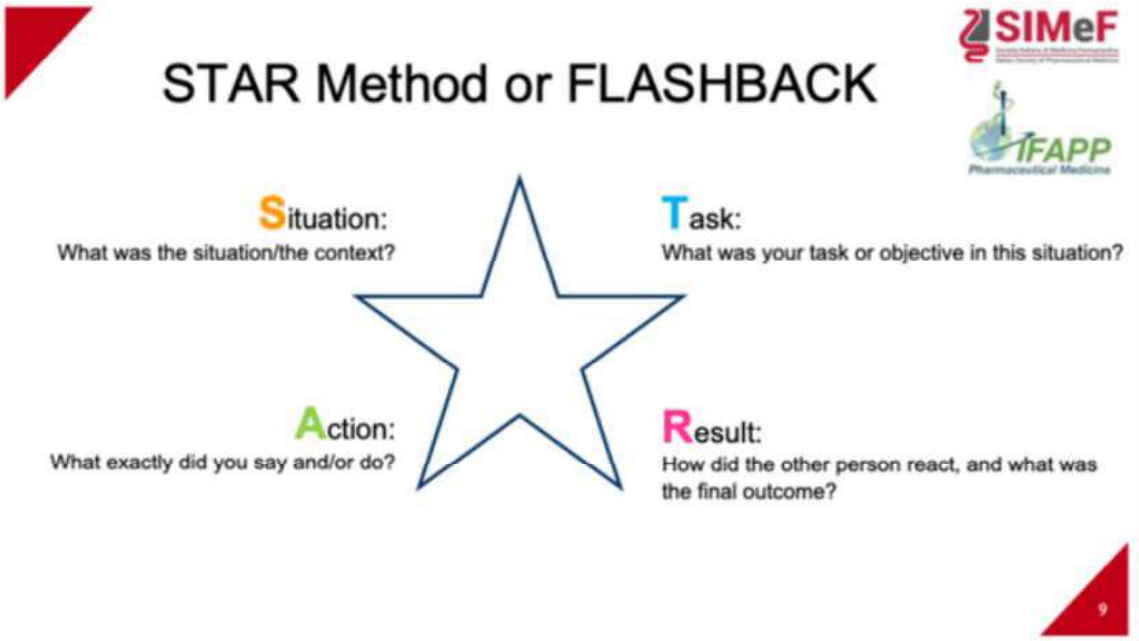


Then Tiziana Musacchio presented the STAR concept



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STAR Method and Micromanagement

With the right questions, the situation is illustrated concretely and with the same level of detail it would have if the events were happening again.

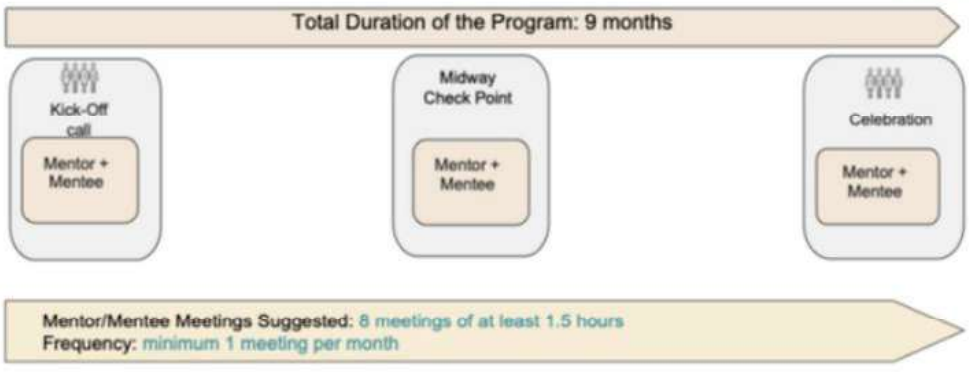
The questions focus on the protagonist's specific actions.
This is meant to help concentrate on specific behaviors.

It is essential that these questions are open-ended, formulated with the aim of understanding and obtaining the most complete picture of the event.

10

... and the timelines of the project:

Program Timelines



11

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as well as the key outcomes

Key Outcomes and Lessons Learned

Impact reported by participants
Clearer professional goals
Improved career planning
Enhanced decision-making skills
Greater confidence in career choices
Broader understanding of the Pharmaceutical Medicine landscape

Lessons learned
Matching is critical for success
Structure supports engagement
Flexibility allows adaptation to individual needs
Mentors benefit as much as mentees from the exchange

Tiziana pointed out that the programme will continue due to the high success rate.

Both Marisa and Tiziana proposed that the mentorship programme be also taken into account by other organisations:

Looking Beyond Italy: A Model for IFAPP

- Opportunities for international collaboration
- Sharing best practices across member associations
- Promoting structured mentoring in Pharmaceutical Medicine
- Supporting professional development globally
- Creating stronger connections between generations and countries
- Building a sustainable mentoring culture within the IFAPP network

The full set of slides and the video recording can be found here https://youtu.be/eief4wvc2hQ

Authors: Birka Lehmann, MD PhD, Chair of IFAPP's Education and Certification Working Group (ECWG),
Marisa Le Donne, PharMD PhD, Clinical Trial Manager Cardio-Renal-Metabolism, Boehringer Ingelheim
Tiziana Musacchio, PharmD PhD, International Medical Affairs Director, Neuroscience Parkinson's Disease, ABBVIE

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IFAPP's Involvement in the WMA Meeting in Rome on the Declaration of Taipei Focusing on Equity and Continuation of Memorandum of Understanding between WMA and IFAPP

Towards equitable participation

The third Open Expert Meeting for the revision of the World Medical Association's (WMA) Declaration of Taipei (DoT) (1) on health databases and biobanks was held on 1 and 2 June 2026 in Rome, Italy, organised by the Pontifical Academy for Life of The Vatican City State; the Israel Medical Association, which chairs the DoT revision workgroup, and the WMA. The focus was on "Equity, Global Challenges and Ethical Considerations" (2). From IFAPP, the authors of this article, Profs Kotone Matsuyama (President-elect of IFAPP) and Chieko Kurihara (Education and Certification Working Group of IFAPP) participated. Profs Liliana Virginia Siede, Argentina, and Nilza Maria Diniz, Brazil, both collaborators for the IFAPP webinar held on 25 May (a Joint Statement from this webinar is found in this issue of IFAPP TODAY) (3), also attended in-person.

Over the two days of the WMA meeting, speakers expressed unanimous calls for transforming inequalities in the context of health databases and biobanks. In particular, almost all speakers recognised the underrepresentation of vulnerable and marginalised peoples as a serious issue. Furthermore, strong appeals were made regarding inadequate benefit-sharing. The difficulties in informed consent associated with the use of artificial intelligence (AI) and definition of ownership of human data and/or samples, as well as the importance of community participation were discussed in depth.

IFAPP's input from Indigenous peoples' perspectives

As these aforementioned points aligned perfectly with the discussions at the IFAPP webinar of 25 May 2026, the collaborators of this webinar actively participated in the debate whilst sharing the outcomes of our webinar. In particular, the issues in the collection of genetic information from Indigenous peoples were not included in the WMA's agenda; therefore, it was significant that we were able to contribute those issues, although resolving them will require several steps. Drs Varvara Baroutsou, Immediate Past President of IFAPP, and Maria Corazon De Ungria, Philippine genetic biologist, speakers of the 25 May 2026 webinar, also joined online and raised critical questions. Perspectives of other advocates in the IFAPP Webinar, Dr Gladness Henna Martinez, Philippine Medical Association, and Pablo Morales Males, Director of the Human Health Evolution Project in Ecuador and America, have been delivered to the WMA meeting by online participants.

What is happening in Africa

The impressive presentation at the WMA meeting by Professor Dr Dominique Sprumont, Vice President of CIOMS (Council for International Organizations of Medical Sciences, of which IFAPP is a member) and Ethics Advisor to the WMA, particularly resonated with the topics of the IFAPP Webinar; it was prepared in collaboration with Dr Jacintha Toohey of the University of KwaZulu-Natal, South Africa. As an advisor to the WMA, Professor Sprumont has continuously made significant contributions to previous revisions of the Declaration of Helsinki (DoH) and the 2016 revision of the DoT. It was particularly important to raise awareness of the situation in which African countries are being pressured by the United States to transfer data and pathogens under unfair conditions (4, 5).

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This issue was raised during the IFAPP webinar by Dr Mantombi Maseme from South Africa. The prohibition of the commercialisation of human biological materials and health data, as well as the definition of global ethical principles for ownership and fair and equitable material transfer agreements (MTA), are difficult challenges, since these principles vary across jurisdictions and cultures. However, an urgent solution is needed through intensive and continuous debates.

Fair and equitable benefit sharing

Furthermore, Professor Jacques Simpore, of the National Council of Genetics at the WHO (World Health Organization) in Burkina Faso, a distinguished scientist in the field of molecular genetics, advanced a compelling argument regarding the manifest inadequacy of current benefit-sharing frameworks. Although the Nagoya Protocol (6), under the auspices of the Convention on Biological Diversity (7), strictly mandates Access and Benefit-Sharing (ABS) between resource users and providers, human genetic resources remain outside its regulatory scope (8). Professor Simpore's advocacy for extending Nagoya-style ABS principles to human-derived biological materials aligns precisely with the paradigm discussed by the IFAPP webinar collaborators, which addresses the foundational grievances raised by Indigenous populations during our session. Consequently, we propose the conceptualisation of a "human variant" of the Nagoya Protocol by fortifying the ABS provisions within the DoT.

Why Equity in dabases and biobanks matters

The debate surrounding the acquisition, storage, and utilisation of data and samples does not involve a lower level of risk to humans compared to clinical trials. Thus, the voices protesting against inequality, injustice, discrimination, and exploitation are being raised even more strongly here than in the discussions on the 2024 revision of the DoH. We must take this reality very seriously.

It is not just that massive data breaches are occurring frequently. This is because mass-traded health data and specimens now hold significant asset value. More importantly, we must acknowledge the reality that, when their samples and data are used in this way, vulnerable and marginalised populations feel that they themselves, as human beings, are being exploited and discriminated against. Many of the challenges in benefit-sharing also fall within the scope of post-trial access under the DoH, and appropriate reflection and classifications of the items of the principles are required for both documents.

Continuation of the MoU between the WMA and IFAPP

The Memorandum of Understanding (MoU) for collaboration between the WMA and the IFAPP was signed in 2017 (9). Now, at the Vatican City meeting, Dr Jacqueline W. Kitulu, Current President of the WMA, and the former and current Secretaries-General of the WMA, Drs Otmar Kloiber and Ramin Parsa-Parsi, and Professor Kotone Matsuyama, President-elect of IFAPP, confirmed that this MoU could be continued without administrative paper work, although the presidents of both organisations have changed several times since then, and the WMA Secretary General Dr Kloiber of 20 years had just been replaced in May 2026 (10).

It was already confirmed in 2023 that the partnership would continue seamlessly during the WMA's meeting on the revision of the DoH in Copenhagen where the Immediate-Past President of IFAPP, Dr Baroutsou was invited as a speaker. The specialty of the current IFAPP President, Dr Eric Klaver, is data science, thus, IFAPP's involvement in the discussions regarding the revision of the DoT is likely to be effective.

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Centre: Dr Jacqueline W. Kitulu, President of the WMA; Right: Dr Otmar Kloiber, the former Secretary General and Dr Ramin Parsa-Parsi, current Secretary General of the WMA. From the Left, Liliana Virginia Siede and Chieko Kurihara

Centre: Dr Ramin Parsa-Parsi, Secretary General of the WMA and at the left, Prof Kotone Matsuyama, President-elect of IFAPP. Left: Ms Sunny Park, WMA Head of Operations. From the right, Chieko Kurihara and Liliana Virginia Siede

Audience with the Pope

The WMA meeting on the revision of the DoT held in Rome was hosted by the Pontifical Academy for Life of the Vatican City State. The day after the meeting concluded, the meeting attendees had the special and precious opportunity to participate in a papal audience alongside tens of thousands of other participants. It was a wonderful surprise and a profound honour that the Pope explicitly mentioned the World Medical Association's conference regarding the Declaration of Taipei, acknowledging our attendance as a significant group within the audience. We extend our deepest gratitude to the President of the Pontifical Academy for Life, Monsignor Renzo Pegoraro, for making this historic and memorable event a reality.

Second from the left: Monsignor Renzo Pegoraro, the President, Pontifical Academy for Life. The others, from left to right: Liliana Virginia Siede, Chieko Kurihara, Jacintha Toohey, Nilza Maria Diniz.

From the right: Kotone Matsuyama, Jacintha Toohey, Nilza Maria Diniz, Liliana Virginia Siede, Chieko Kurihara

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Next Steps

The next WMA meeting on the DoT is scheduled to be held in Oslo, Norway, on 14 and 15 September 2026, and registration for in-person attendance is now open. Past records of the DoT conferences, along with future schedules, can be accessed in the following link:
https://www.wma.net/what-we-do/medical-ethics/declaration-of-taipei/

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10. Varvara Baroutsou, Chieko Kurihara, Kotone Matsuyama. IFAPP Acknowledges Dr Otmar Kloiber's Retirement and Welcomes Dr Ramin Parsa Parsi as WMA Secretary General. Page 10-11.

Photo Credit: Photos from the WMA meeting were taken and provided by the WMA.

Authors:
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Chieko Kurihara, Education and Certification Working Group, IFAPP, Editor-in-Chief, Clinical Evaluation, Japan

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Upcoming IFAPP Webinar: Ethics of genome editing and iPS cells: experiences from South Africa and Japan

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Bios and references of presenters

Yoshiko Saito, Holding a Master of Business Administration (MBA) in Social Design Studies, from Rikkyo University, Japan, she is a breast cancer survivor and PPI (patient public involvement) practitioner bridging lived experience with bioethical inquiry. Following her diagnosis in 2015, she became actively engaged in peer support and, in 2022, joined the Japanese Institute for Public Engagement (Ji4pe), where she now leads the Bioethics Working Group. Collaborating with patient communities and multidisciplinary experts, she is currently exploring ethical questions surrounding cutting-edge technologies. She will present her perspectives on the science of manipulating cells towards healthcare that supports people, considering the spirit of the Helsinki Declaration and the Ethics of Care in the context of the future of iPS Cells research and its clinical application.

Reference for the lecture

Kurihara C, Saito Y, Kai H, et al. Patient Public Declaration of Research Ethics: Opinions and proposals from patients, public and communities on research ethics. In: Kurihara C, Greco D, Dhai A, editors. The 2024 Declaration of Helsinki: Global Efforts Towards the Highest Ethical Standards. Singapore: Springer; 17 September 2025. p. 205-24.

Safia Mahomed is a Professor at the University of South Africa's (UNISA) School of Law. She is an admitted attorney in the North Gauteng High Court. She obtained her LLM (Master in Laws) from UNISA in 2013 and her PhD from the University of the Witwatersrand (WITS) in 2018. Her research interests focus on questions around health law and bioethics, with specific emphasis on identifying gaps in South Africa's healthcare framework and developing regulatory measures to address them. Her current research trajectory involves an examination of the ethical and legal considerations for human tissue transfer and artificial intelligence in healthcare. Safia was awarded UNISA's Principal's Prize for excellence in research in 2019. She is a current member and former Chair of UNISA's Biotechnology and Medical Law Flagship, on the editorial committee at the South African Journal on Human Rights, a member of the Biobanks Ethics Committee at the University of the Witwatersrand and a member of the South African Medical Association's task team for AI in healthcare.

References for the lecture

Mahomed S, Ramsay M, Pepper M, De Vries J, Flack-Davison E. Section on heritable human genome editing withdrawn from the National Health Research Ethics Council Guidelines. S Afr Med J. 2025 Aug 1;115(7):e3967. doi: 10.7196/SAMJ.2025.v115i7.3967.

Ramsay M, Pepper M, De Vries J, Mahomed S, Flack-Davison E. Heritable human genome editing in South Africa - time for a reality check. S Afr Med J. 2025 Feb 18;115(1):e2872. doi: 10.7196/SAMJ.2025.v115i1.2872.

Click here to register

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WOMA Milan 2026: Navigating the New Frontiers of Life Science

On 25 and 26 June 2026, Allianz MiCo in Milan hosted the WOMA Forum (https://womaforum.com), an international event conceived to explore the forces that are reshaping health, science, technology and society. Its agenda brought together political leaders, scientists, physicians, technologists and experts in human behaviour, reflecting an increasingly evident reality: the future of life science will emerge from the interaction between geopolitics, digital transformation, artificial intelligence (AI), genome engineering, regulation and human decision-making.

For professionals working in Pharmaceutical Medicine, this interdisciplinary perspective is no longer optional. Drug development now takes place within systems exposed to geopolitical fragmentation, supply-chain vulnerability, technological acceleration, new forms of data generation and growing public expectations. At the same time, scientific possibilities are expanding faster than many institutions can absorb them.
WOMA provided a framework for understanding how different forces are converging, and why leaders in life science must learn to connect them.

Author Francesco Butti with Prof. Jennifer Doudna, Nobel Prize in Chemistry in 2020, at the event

Geopolitics

José Manuel Durão Barroso introduced one of the broadest perspectives of the Forum: the need to understand geopolitics as a structural determinant of our future.
Former Prime Minister of Portugal and President of the European Commission from 2004 to 2014, Barroso has spent much of his career at the intersection of national politics, European integration and global governance. His contribution was particularly relevant at a time when Europe is confronting war on its borders, strategic competition between the United States and China, demographic decline, economic pressure and an increasingly fragmented international order.

Barroso described the present as a period of global disorder rather than a stable transition. He has argued that Europe can no longer remain a "geopolitical teenager": it must assume greater responsibility for its security, competitiveness and strategic autonomy. Europe, in his view, must find its position in a rapidly changing international system while addressing its relative loss of competitiveness and the ageing of its population. This perspective is highly consequential for life science, since, when geopolitical relations deteriorate, science does not remain untouched.

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For pharmaceutical organisations, geopolitical literacy is therefore becoming a practical capability. Portfolio decisions and development plans can no longer be based only on epidemiology, scientific feasibility and commercial potential. They must also consider political stability, infrastructure resilience, access to talent, societal trust and the changing geography of innovation.

Europe faces a particularly delicate challenge. It has world-class science, strong healthcare systems and a sophisticated regulatory framework, but it must compete with regions capable of mobilising capital, infrastructure and innovation at greater speed. Strategic autonomy should not mean scientific isolation or protectionism. Rather, it should mean remaining open while avoiding dangerous dependencies.

For life science, this requires sustained investment in research ecosystems, advanced manufacturing, digital infrastructure and professional skills, combined with international cooperation among trusted partners.

Technology in Healthcare

Dr Bertalan Meskó, widely known as "The Medical Futurist," brought the discussion from the global system to the transformation of healthcare itself.

A physician with a PhD in genomics, Dr Meskó is the Director of The Medical Futurist Institute and has built his work around a central question: how can technologies that once appeared to belong to science fiction become useful, accessible and humane components of medicine?

His perspective is distinctive because he does not treat digital health as a catalogue of devices. AI, wearable sensors, digital biomarkers, robotics, virtual reality, remote monitoring and patient-generated data matter only when they improve health outcomes, access to care or the experience of patients and healthcare professionals.

Healthcare systems are frequently attracted by technological novelty, yet implementation remains slow and uneven. Dr Meskó has openly reflected on the barriers delaying the clinical integration of AI and other digital tools: regulation, bureaucracy, limited interoperability, workflow disruption and, above all, trust. A technically impressive solution may fail if clinicians do not understand it, patients do not accept it or organisations cannot integrate it into real practice.

For Pharmaceutical Medicine, the implications are substantial. A recurring principle in Dr Meskó's work is the combination of technology and the human touch. The future of medicine should not be framed as competition between clinicians and machines. It should be understood as a redesign of their relationship.

Automation should reduce administrative burden, expand cognitive capacity and allow healthcare professionals to devote more time to judgement, communication and empathy. Patients, meanwhile, should not remain passive recipients of innovation. They should become informed participants with greater access to their own data and a stronger voice in decisions affecting their health.

This patient-centred transformation requires more than the procurement of new tools. It demands cultural change. Organisations must develop digital literacy, involve intended users early, test technologies in real clinical environments and distinguish between experimental promise and demonstrated value.

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The most successful innovations may not be the most spectacular. They will be those that fit responsibly into the complex reality of healthcare.

Artificial Intelligence

Zack Kass addressed perhaps the most pervasive theme of the present moment: AI as both a threat and an opportunity.

Former Head of Go-To-Market at OpenAI, Zack Kass has become a prominent advocate of what he calls the next "AI renaissance." His position is deliberately optimistic, although not naïve. He argues that excessive pessimism can become strategically paralysed, preventing organisations and societies from actively shaping technology and distributing its benefits.

The public debate on AI is often organised around fear: job displacement, misinformation, surveillance, concentration of power, loss of human control and the possibility that increasingly autonomous systems may behave unpredictably. These concerns are legitimate. Focusing only on risk, however, produces an incomplete picture.

Zack Kass invites audiences to move from asking only what AI might take away to considering what it might make possible. In his view, technology should contribute to solving large societal challenges and reducing the costs of essential services, including healthcare and education. His central provocation is that the decisive question is not simply what AI will do to us, but what we will choose to do with AI.

Adoption is not determined by technical capability alone. It depends on societal readiness, incentives, institutional trust, organizational design and leadership. A system may perform brilliantly in a controlled test and still fail because people do not understand its purpose, fear its consequences or see no benefit in changing established behavior. Zack Kass has therefore identified social readiness, not merely model performance, as one of the central barriers to meaningful AI adoption.

The opportunity is not merely greater efficiency. AI could support a different model of research, augmenting the capacity of scientists, clinicians and pharmaceutical professionals. Yet human expertise must remain actively engaged. AI can generate answers, but people must still define the right questions, recognise uncertainty, evaluate context and accept responsibility for consequences.

Zack Kass's optimism is therefore best understood as a call to self-determination. The future is not predetermined by technology. It will be shaped by the values embedded in its design, the distribution of its benefits and the courage of institutions to use it intelligently.

Genome Editing

The scientific summit of WOMA was represented by Dr Jennifer Doudna, Professor at the University of California, Berkeley, USA, co-inventor of CRISPR-Cas9 (1) genome editing and recipient (see photo at top of the article), with Emmanuelle Charpentier, of the 2020 Nobel Prize in Chemistry.

Her work transformed a bacterial defense mechanism into a programmable tool capable of cutting DNA (2) at a selected location. Biology moved from an era in which the genome could primarily be observed and interpreted to one in which it could be intentionally modified.

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The opportunities are immense. Genome editing can address disease at its molecular origin rather than only treating its downstream consequences. The first clinical successes in haemoglobinopathies have demonstrated that the concept can translate into transformative therapies. Beyond ex-vivo editing, the field is advancing towards in-vivo approaches, more precise editing systems, improved delivery technologies and potential applications across genetic, oncological, infectious and metabolic diseases.

Dr Doudna's scientific activity extends beyond the original CRISPR-Cas9 system. Her laboratory investigates novel CRISPR-associated proteins, editing mechanisms, anti-CRISPR molecules and applications in mammalian systems, plants and fundamental biology. The continual discovery of new biological mechanisms reveals why CRISPR should not be understood as a single technology, but as an expanding platform and toolbox.

The revolution also reaches beyond medicine. Genome editing may contribute to more resilient crops, sustainable agriculture, new biological manufacturing processes and reduced environmental impact. It could help societies respond to climate change and food insecurity.

The same capacity to rewrite biological information, however, inevitably raises ethical questions.

Dr Doudna has consistently maintained that scientific possibilities must be accompanied by public deliberation and responsible governance. Somatic editing intended to treat an individual patient differs fundamentally from heritable editing of embryos, which could transmit genetic changes to future generations.

Heritable editing raises unresolved questions about safety, consent, inequality, enhancement and the boundaries of legitimate intervention. The challenge is not simply to determine whether a genetic change can be made, but whether it should be made, under what conditions and with whose consent.

Another major concern is access. A therapy may be scientifically revolutionary yet socially limited if its cost, complexity or infrastructure requirements place it beyond the reach of most patients. The next chapter of genome editing will therefore depend not only on precision and clinical efficacy, but also on scalable manufacturing, delivery, affordability and global availability.

For pharmaceutical professionals, CRISPR exemplifies the convergence of discovery, clinical development, ethics and public policy. Its development programmes require long-term follow-up, sophisticated approaches to off-target assessment, careful benefit–risk evaluation and transparent engagement with patients and society.

Technology invites extraordinary ambition, but also scientific humility. Humanity is gaining the ability to intervene in the code of life; wisdom and governance must advance alongside technical capability.

Human Presence in an Age of Complexity

After geopolitics, digital medicine, AI and genome editing, Dr Amy Cuddy brought the Forum back to the human being.

A social psychologist, bestselling author and internationally recognised speaker, Dr Cuddy studies power, presence, belonging and the way people respond in high-stakes situations. Her work asks why individuals sometimes act with confidence and authenticity, while at other times they withdraw, freeze or silence themselves.

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This perspective is crucial because complexity is not managed by analytical frameworks alone. It is managed by people, often under pressure, uncertainty and conditions of incomplete information.

For Dr Cuddy, presence is not theatrical confidence, dominance or the absence of fear. It is the capacity to remain connected to one's values, abilities and intentions when the stakes are high. Personal power is not status over other people; it is the ability to regulate oneself, speak, contribute and act.

Dr Cuddy's work on warmth and competence is also relevant to leadership. Expertise alone does not generate trust. People evaluate both the intentions and the capabilities of those who lead them. During periods of transformation, leaders must therefore communicate direction and humanity together. They cannot eliminate uncertainty, but they can help people move through it. Trust is not a soft accessory to scientific performance. It is part of the infrastructure that allows teams to cooperate, learn and respond to complexity.

The greater the power of our technologies, the more important these human qualities become. AI may expand cognitive capacity, and genome editing may enlarge biological agency, but neither can determine what is worth pursuing.

That requires values, courage, dialogue and the ability to remain fully present amid complexity.

A New Forum for Milan, and for Life Science

WOMA Milan demonstrated that the most important questions for life science no longer fit neatly within disciplinary boundaries.

As the first life-science event in Milan of this nature, WOMA created something genuinely distinctive: a meeting place where science, technology, policy, business and human behaviour could be considered as interconnected elements of the same future.

It was an extremely inspirational event, bringing together approximately 1,000 participants, 200 companies and 30 sponsors. More importantly, it invited the life-science community to look beyond the boundaries of its traditional expertise.

The Forum's deepest message was that progress will depend on our capacity to connect political, scientific, technological, ethical and human intelligence. In a period of extraordinary acceleration, WOMA reminded us that the preparation for the future begins by learning to see the whole system.

Abbreviations:

1. CRISPR: clustered regularly interspaced short palindromic repeats
2. CRISPR-Cas9: CRISPR-Cas9-associated protein 9 is a DNA cutting endonuclease that is part of the CRISPR immune system in bacteria and archaea
3. DNA: deoxyribonucleic acid

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Mark Your Calendar with the Upcoming Free Webinar:

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