



Above: Mawell Sameh, Foundation Medical Lead Sanofi Egypt & Sudan

STAY CONNECTED TO SUCCESS THROUGH OUR COMMUNITY SPOTLIGHT SERIES

The Academy is proud of the accomplishments of its alumni, faculty, and community. We are excited to dedicate a section of our newsletter to updates from our valued community members.

Our first featured spotlight is that of IFAPP Academy alumna Mawell Sameh, Foundation Medical Lead for Sanofi Egypt and Sudan. Keep reading on page 2 to hear more about her prestigious advancements in Medicines Development.

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INTRODUCING: IFAPP ACADEMY'S COMMUNITY SPOTLIGHT SERIES



**“Courageous leaders never know the
“Impossible dream”**

**Their strategic thinking enlightens the way to
seize valuable opportunities; their passion
ignites the starting spark on the road of
success; and they dare to overcome tough
challenges with resilience.
They spread their wings and fly with their
dreams above and beyond the horizon.”**

Mawell Sameh, Foundation Medical Lead
Sanofi Egypt & Sudan

"My professional development was one of the key success factors in my career. I was honored to accomplish the Certification Program in Medicines Development from King's College, London and IFAPP Academy, in 2020, where I learned a lot about the core cognitive competencies for an effective performance in medicines development and medical affairs from top experts in this arena.

In 2021, I got promoted to a more senior position, becoming a Foundation Medical Lead in Sanofi responsible for foundation portfolios in Egypt and Sudan, which is a new adventure in managing diversified portfolios in two countries and leading the digital transformation in the interactions with HCPs and patients through innovative projects, yet the learnings I have earned from IFAPP Academy in one year are worth ten years of learning! It has supported me a lot, not only while working on our projects, but also in my day-to-day practice."

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Did you know that 90% of our past students agree that the program has had a significant impact on their work and enriched their life?

[Click here](#) to complete your application for the 2023 IFAPP Academy-King's College London Medical Affairs in Medicines Development Certification Program.

PROFESSIONAL IDENTITY & MEDICINES DEVELOPMENT

"My wealth of experiences, relationships, knowledge, skills, values and ethics were the pillars of my Professional Identity when I was a physician, and they are now that I'm a Medical Affairs professional but enriched with what I have been able to learn and experience in recent years. My ethics, strong empathy, trust in others, ability to communicate and tendency to socialize, are skills and qualities that I have honed over time, on which I have worked since my school/university career and with the experiences I have had, and that have allowed me to manage the change and perfectly fit in the new professional field.

Now Medical Affairs is changing and as reported in the McKinsey paper¹ the evolution of Medical Affairs, with its new strategic role, will increasingly lead to a broader view of our role and tasks, with hopefully positive consequences for my path and my Professional Identity.

"The sense of belonging that comes from Professional Identity can lead to job satisfaction... " (Rasmussen P et al.)² and I am proud to say that at this point I am satisfied of my personal and professional life, regarding who I'm and what I do! I enjoy talking about my work, explaining my activities and I'm proud of what I do. I'm happy to be able to contribute to help patients and give them hope, especially in a particular dimension like rare diseases. But I know this is a point along the way and I need to continue with the same belief and resilience to achieve other goals, continuing to face challenges and get out of my comfort zone. This course, and particularly module 7 by results of HBDI assessment and Personal Resilience Profile, had a high impact on my future development and how my Professional Identity might change. I have learned some key strategic concepts for the foundations of leadership and I'm even more convinced that I would like to become a manager, able to create the right situations for everyone to express themselves at their best, but this will be possible only if I will be able to create for myself such a condition, continuing to work on myself."

- Matteo Napoleone



Matteo Napoleone is a Medical Doctor and works as Medical Scientific Relations Advisor in Rare Disease at Pfizer Italy. He joined Pfizer in January 2020 after 4 years' experience in Diagnostic Radiology.

To read the essay in its entirety, [please click here](#).

NEWS FROM THE EMA: ACCELERATING CLINICAL TRIALS IN EUROPE

The European Commission (EC), the Heads of Medicines Agencies (HMA) and the European Medicines Agency (EMA) have published the 2022-2026 workplan of the Accelerate Clinical Trials in the EU (ACT EU) initiative. The workplan has been prepared based on the recommendations of the European medicines' agencies network strategy to 2025 and the European Commission's Pharmaceutical Strategy for Europe.

The initiative launched in January just before the Clinical Trials Regulation (CTR) became applicable and seeks to promote the development of high-quality, safe and effective medicines by strengthening



the European clinical trials environment. The workplan is structured in line with the ten priority actions of ACT EU and highlights key focus areas, such as innovation in clinical trials, robust methodologies, and collaboration across stakeholders.

Continue reading [here](#).

NEWS FROM THE BIOTECH SECTOR: EMERGING CONTRIBUTIONS TO INNOVATION



The IQVIA institute, part of the IQVIA company, the largest global CRO, produces several reports related to pharmaceutical and biotech companies. Their latest report is devoted to biotech companies and the role they have on the research and development of new drugs. One key highlight of the report is that in the last twenty years, the share of EBPs in the R&D pipeline has doubled and is continuing to grow!

“The majority of biomedical innovation is developed by emerging biopharma (EBP) companies, many of which have never marketed a therapy before. Over time, those companies either successfully bring their products to market or, in many cases, their assets or whole companies are acquired by others.”³

Continue reading [here](#).

NEWS FROM CIOMS

We are pleased to share the CIOMS report on “Patient involvement in the development, regulation and safe use of medicines”, which is available as a free download.

The report is the result of four years of work with patient group leaders, academics, industry experts, regulators and other stakeholders, and the EMA.

It describes the importance of systematically involving patients throughout a medicine’s lifecycle, from early development through the regulatory process to ongoing monitoring and safe use in everyday healthcare, and provides a comprehensive overview of current knowledge regarding the benefits of patient involvement and existing initiatives, with examples and recommendations.



It also addresses the remaining challenges and practice gaps. The aim of the report is to prompt readers to implement its best practice recommendations according to how well they fit in with their organizational and national needs.

Continue reading [here](#).

Download the full report [here](#).

CLINICAL TRIALS SUGGEST BENEFIT OF POLYPILL FOR CVD



Several years ago, The Lancet suggested the potential benefits of the marketing of a so-called “polypill”, a medication based on the combination of aspirin (100mg), ramipril (2.5, 5 or 10 mg) and atorvastatin (20 or 40 mg), indicated for the secondary prevention of myocardial infarction. The aim was to increase patients’ compliance, but no company was interested in investing in this combination product based on 3 ingredients whose patent had expired. The Lancet⁴ and New England Journal of Medicine⁵ published two new clinical trials, wherein the results once again support the clinical benefits of a polypill. Click below to read some of the key findings of the trials.

Continue reading [here](#).

SWITCHING AMONG BIOSIMILARS

The marketing authorization and the commercialization of the first biosimilars raised an important clinical dilemma: is it safe for patients the switch from the originator to a biosimilar, and even more, is it safe the switch among biosimilars? For many years the scientific community was in doubt, as we know that a biosimilar (as the word correctly states) is never identical to the originator. Initially, clinicians took a v prudent approach and produced guidance to avoid the switch.

For many years patients who started a biological agent were advised to continue with the same brand.



Over the last decades, more evidence accumulated that supports the conclusion that the switch results in no harm for the patients.

Continue reading [here](#).

ARE YOU A PART OF OUR GLOBAL COMMUNITY?

Want to be featured in a future edition of the Academy newsletter? Do you have an update you'd like to share with the IFAPP Academy network? We invite you to share a professional achievement, job transition, or personal milestone and welcome your submissions.

Email your news and updates to community@ifappacademy.org.





HIGHLIGHTS OF AIDS 2022

The HIV world conference, held in Montreal in 2022, was the first in-person International AIDS Society meeting since 2019. Amidst funding concerns and overshadowed by visa issues, it was a slightly subdued affair. This article from the Lancet provides highlights and takeaways from the conference including the denial of VISAs to potential attendees, STI prevention with doxycycline, treatment of HBV and HIV infections, and the use of PrEP in pregnancy.⁶

Continue reading [here](#).

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Thanks for reading! The IFAPP Academy Newsletter is published bi-monthly and is compiled by the following:

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