



Above: Mohamed Amine Harti, MERA Hospital Medical Lead for Pfizer Middle East, Russia, CauCAR & Africa

COMMUNITY SPOTLIGHT: PURPOSE AND PROFESSIONAL GROWTH AS AN ACADEMY ALUM

The Academy is proud of the accomplishments of its alumni, faculty, and community. We are delighted to share updates, accomplishments, and reflections from our valued community members.

This month's community spotlight is on Mohamed Amine Harti, MERA Hospital Medical Lead for Pfizer Middle East, Russia, CauCAR & Africa. Read Mohamed's incredible career updates on page 2.

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IFAPP ACADEMY'S COMMUNITY SPOTLIGHT SERIES

“ My decision to obtain my Professional Certification, Medical Affairs in Medicine Development from IFAPP Academy & King’s College London in 2019 was aligned with my career goal of continuous learning to allow me to acquire new capabilities. The experience was one that I found challenging but very rewarding and I am confident my newly acquired capabilities will be put to excellent use in following my purpose in serving patients in Africa, Middle East and hopefully across the globe.”



**Mohamed Amine Harti,
MD, MBA**

MERA Hospital Medical Lead
Middle East, Russia, CauCAR & Africa
Pfizer

"As I reflect on my career in Medical Affairs, I have always been driven by my purpose to always serve patients through generating and communicating critical evidence that facilitates access to solutions and breakthroughs that impact their lives. Keeping my focus on my purpose has allowed me to grow from a country colleague in North Africa to my current role of a regional colleague for Africa and the Middle East. My current role is a significant new chapter for me which enables me to continue to grow, learn and contribute across diverse healthcare environments and cultures.

Within the Biopharma industry, Medical Affairs is increasingly playing a critical role in the purpose of assessing the environment and identifying unmet needs in order to propose and implement solutions that drive effective scientific engagements with key stakeholders including healthcare professionals, patient organizations and scientific institutions. My decision to obtain my Professional Certification, Medical Affairs in Medicine Development from IFAPP Academy & King’s College London in 2019 was aligned with my career goal of continuous learning to allow me to acquire new capabilities. The experience was one that I found challenging but very rewarding and I am confident my newly acquired capabilities will be put to excellent use in following my purpose in serving patients in Africa, the Middle East, and hopefully across the globe."

CIOMS AND IFAPP ACADEMY COLLABORATION

The CIOMS Secretary, Dr. Lembit Rago, launched an initiative to draft a book related to 'Recommended Standards of Education and Training for Health Professionals Participating in Medicines Development' and in doing so, requested the collaboration of many professionals representing academic institutions, pharmaceutical companies, learned societies, PharmaTrain, regulatory bodies such as EMA and FDA, the World Medical Association, and many more.

Several members of the Academy are also collaborating on this initiative.



These include Dr. Honorio Silva, Dr. Gustavo Kesselring, Dr. Peter Stonier, Dr. Pravin Chopra, Dr. Sandor Kerpel-Fronius, and Dr. Domenico Criscuolo. The professionals aim to finalize the five-chapter book by June 2023.

[Continue reading here.](#)

NEWS FROM THE EMA: PUBLIC CONSULTATION FOR DATA QUALITY FRAMEWORK



The European Medicines Agency has launched a public consultation for the first release of the Data Quality Framework for the EU medicines regulation.

The draft Data Quality Framework document provides general considerations that can be applied to a wide range of data sources for the purpose of characterizing and assessing data quality for decision-making. It also outlines what data quality actions and metrics can be put in place in different regulatory decision-making scenarios and introduces maturity models for the characterization of data quality for regulatory purposes.

[Continue reading here.](#)

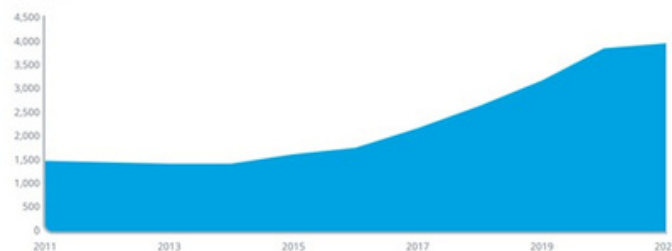
BIOPHARMA AND DRUG DEVELOPMENT

The IQVIA Institute recently published a report on biopharma companies. Important findings include:

- There are nearly 4,000 products in clinical development by emerging biopharma companies, which does not include research programs where emerging biopharma companies may be partnering with larger companies.
- Since 2011, the emerging biopharma pipeline more than doubled, growing 165% with much of that growth coming in the last five years.
- Larger companies have seen slower growth over the last five years with large pharma averaging 2% growth annually, mid-sized companies averaging less than 1% growth annually and small companies averaging 3% growth annually.

Emerging biopharma companies are currently developing nearly 4,000 drugs, more than double the number in 2016

Exhibit 5: Number of pipeline products Phase 1 to regulatory submission by emerging biopharma companies, 2011-2021



Source: IQVIA Pipeline Intelligence, Dec 2021; IQVIA Institute, May 2022.

- The emerging biopharma R&D clinical pipeline has grown on average 18% annually over the last five years, compared to just 11% for the pipeline across all company sizes, highlighting the increasing importance of emerging biopharma to the development of new therapies.

Continue reading [here](#).

COP27 CLIMATE CHANGE CONFERENCE: URGENT ACTION NEEDED FOR AFRICA AND THE WORLD



The climate of our planet is rapidly changing, and this may have serious global consequences. In particular, Africa seems to be the continent more seriously affected by climate change. A group of editors of African Medical journals composed an editorial and we have included some key insights from the editorial below.

“Wealthy nations must step up support for Africa and vulnerable countries in addressing past, present, and future impacts of climate change. The 2022 report of the Intergovernmental Panel on Climate Change paints a dark picture of the future of life on earth, characterized by ecosystem collapse, species extinction, and climate hazards such as heatwaves and floods.”¹

Continue reading [here](#).

MIGRAINE RESEARCH IN THE 21ST CENTURY

“The migraine landscape has evolved over the past 20 years, with refinements in classification and research design, a surge in new treatments developed with intent and not by chance, the emergence of 21st-century migraine genetics, and a refocusing on peripheral and central pain mechanisms.

One notable advancement has been the development of the International Classification of Headache Disorders (ICHD), presently in its third edition: the ICHD has provided standardized case definitions and nomenclature for migraine, including the first definitions of chronic migraine and medication...



...overuse headache, as well as uniform criteria for patient selection in worldwide clinical research.”²

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.



CIRCULATING POLIOVIRUS IN NEW YORK- NEW INSTANCE OF AN OLD PROBLEM

The Academy newsletter recently included a publication speaking to the importance of vaccination to eliminate infectious diseases as well as the report that polio was very close to its eradication. But what happened? The war in Pakistan and Afghanistan halted vaccination campaigns, and the virus took the opportunity to continue its spread, arriving in the UK and the United States.

As [this](#) article in the New England Journal of Medicine states, “The United States and the United Kingdom are now experiencing outbreaks of imported poliovirus similar to those that dozens of other countries have seen over the past 6 years, and for the same reason-



under-vaccination. In the United States, the indigenous wild polioviruses (WPVs) had most likely been eliminated by the early 1970s, if not earlier, thanks to rapid improvement in vaccine coverage with the attenuated oral poliovirus vaccine (OPV)."³

Continue reading [here](#).

PÄÄBO WINS NOBEL PRIZE FOR WORK ON HUMAN EVOLUTION



It is well-known that the 2022 Nobel Prize was won by Dr. Svante Pääbo, a Swedish geneticist, for his studies on human evolution. But why are these studies so important, and how can his discoveries be put to practical use? This article from the Lancet includes some answers to these questions. Namely, Dr. Pääbo’s work examines a fundamental question of human physiology: what is it that makes us human?

According to Dr. Pääbo, “I never imagined that we would be talking⁵ about the Neanderthals”, he said. “Sometimes I have to take a step back and remind myself of how cool this all is. We are comparing modern-day human beings at a molecular level with extinct forms of humans that walked the earth tens of thousands of years ago.”⁴

Continue reading [here](#).

A USEFUL GUIDELINE FOR THE USE OF REAL-WORLD EVIDENCE (RWE) DATA

The European Medicines Agency has published the first global guidance on metadata to empower systematic integration of real-world evidence in medicines regulation, and is entitled Good Practice Guide for the use of the Metadata Catalogue of Real-World Data Sources.

The guide provides recommendations on how to use the catalogue of real-world metadata that is currently being built and in late 2023 will replace the existing catalogue of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP). The guide will help to identify suitable real-world data sources for studies and describes the metadata elements that will be used.



Real-world data are observational data stored in repositories such as electronic health records and disease registries. Metadata characterize real-world data and are essential to improve data discoverability, create a clearer understanding of their meaning and achieve greater reliability and quality when using them to improve the evidence available for benefit-risk decisions.

Continue reading [here](#).

EMERGING BIOPHARMA'S CONTRIBUTION TO INNOVATION



The link below takes readers to emerging biopharma companies regarding therapeutic areas with the most ongoing activities. By far, oncology is the area where most companies are investing their efforts.

This is due in part to strong medical needs, as available therapies are useful but unfortunately frequently fail. It is also due to a better understanding of the pathogenesis of many cancers, which now allows the design of targeted therapies.⁵

Click [here](#) to read more.



THE IFAPP ACADEMY GLOBAL FELLOWSHIP IN MEDICINES DEVELOPMENT

The IFAPP Academy has inaugurated a Global Fellowship of experts and those experienced in the development of medicines with the aim to advance the disciplines involved in pharmaceutical medicine/medicines development to gain competence and professional identity amongst their membership. In 2020, 117 individuals from 24 countries received the Global Fellows in Medicines Development (GFMD) award. [Click here](#) to read more about becoming a Global Fellow in Medicines Development.

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