IFAPP academy
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PROFESSIONAL IDENTITY AND MEDICINES DEVELOPMENT: INSIGHTS FROM ACADEMY ALUMNI

The Academy remains committed to the exploration of one's Professional Identity within Medicines Development. To that end, we are pleased to share a well-written essay from Academy alumni Matteo Bonetto Gambrosier. We sincerely thank Matteo for his contributions to the IFAPP community.

Continue reading on page 2 to read more from Matteo as he discusses the development of his own Professional Identity and what it means for his current and future professional endeavors.

TABLE OF CONTENTS

IFAPP academy

Matteo graduated as an MD at Sapienza University of Rome in Italy in 2013. After working for a few years as a physician in Italy, he moved to the UK to start surgical training in urology. In 2018, Matteo joined Pfizer with a hybrid role of MSL-Medical Advisor in Rare Disease. He launched a breakthrough medication in rare cardiology (ATTR amyloidosis). He is currently working as a Medical Scientific Advisor Line Manager (formally Medical Manager) role in ATTR amyloidosis. He uses his IFAPP knowledge to support upcoming launches of gene therapies.

Matteo Bonetto Gambrosier, MD

Medical Scientific Advisor Line Manager
Pfizer, Italy

CONT'D: PROFESSIONAL IDENTITY & MEDICINES DEVELOPMENT

"During this academic program, I understood what my interests are, what I don't like and in which direction I want to walk. Going beyond the routine and looking into soft skills, together with my medical knowledge, will help me create my story, within and beyond the company, to describe who I am and how I work. My additional interests in digital, economics, patient associations, and market access will eventually provide additional skills that allow me to find a professional identity in some pharma companies.

My development will be focused on managing people and budgets, setting very high goals, and empowering my team to work at their best. The medicines development academic program with the IFAPP Academy really gave me the opportunity to gain an overall picture of what characteristics are needed in a team, and allowed me to reflect on what my personal ones are."

Click here to read the essay in its entirety.

FAUCI RESPONDS TO MUSK'S TWITTER ATTACK

Last December, Anthony Fauci stepped down as director of the US National Institute of Allergy and Infectious Diseases (NIAID) after more than 38 years in the post and 54 years at its parent organization, the US National Institutes of Health (NIH). He has led the institute under seven US presidents and overseen its research and response to the HIV/AIDS epidemic, the Ebola outbreak that began in West Africa in 2014 and the COVID-19 pandemic.

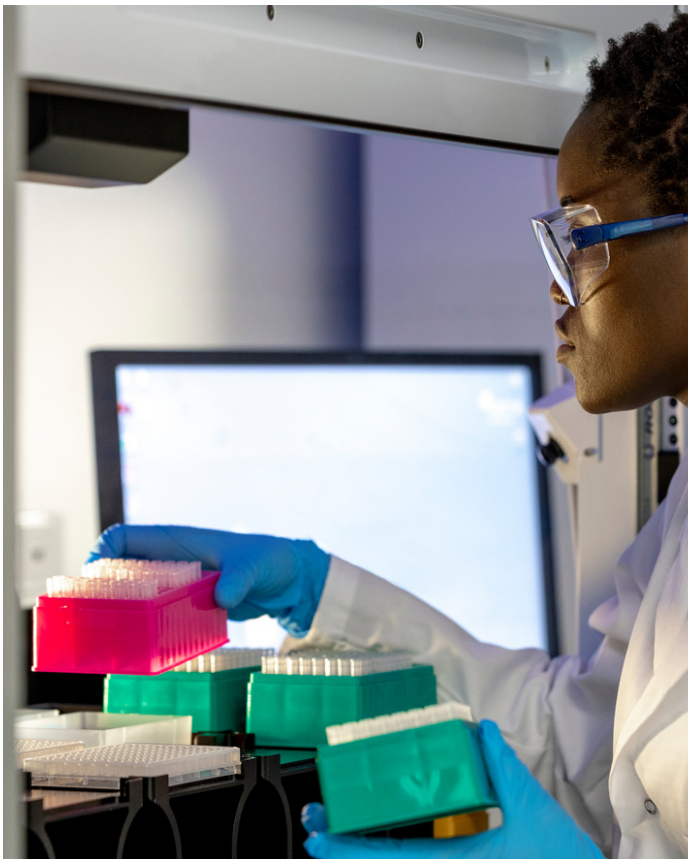
The 81-year-old physician-scientist became a household name during the pandemic, during which he was revered as a trusted source of some and disparaged by others, including former US president Donald Trump, who saw his advice as inconsistent and overbearing.

On 11 December, he was attacked on Twitter by Elon Musk, who took over the social media platform in October 2022.

Fauci spoke to Nature about Musk's comments, the pandemic and his own legacy.[1]

Continue reading here.

NEWS FROM THE FIGHT AGAINST CANCER



The end of 2022 saw several initiatives in oncology in Europe that, if successfully implemented, could radically improve European cancer research and patient care.

The recently launched European Groundshot Commission, which includes new data on cancer research activity and outcomes across Europe during the past 12 years, proposes an evidence-based, patient-centered cancer research roadmap for Europe.

The Commission shows that cancer is the leading cause of premature mortality and a major economic burden in many European countries and highlights notable disparities in optimal cancer control between western European and central and eastern European countries. [2]

Continue reading here.

CNS NEWS: LECANEMAB IN EARLY ALZHEIMER'S DISEASE

The accumulation of soluble and insoluble aggregated amyloid-beta (Aβ) may initiate or potentiate pathologic processes in Alzheimer's disease. Lecanemab, a humanized IgG1 monoclonal antibody that binds with high affinity to Aβ soluble protofibrils, is being tested in persons with early Alzheimer's disease.

In an 18-month, multicentre, double-blind, phase 3 trial, persons aged 50 to 90 years of age were selected with early Alzheimer's disease (mild cognitive impairment or mild dementia due to Alzheimer's disease) with evidence of amyloid on positron-emission tomography (PET) or by cerebrospinal fluid testing.

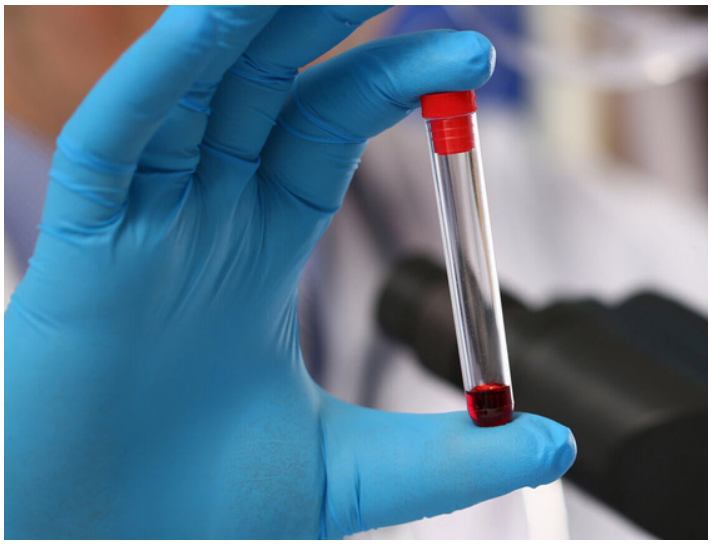
Participants were randomly assigned in a 1:1 ratio to receive intravenous lecanemab or placebo. The primary endpoint was the change from baseline at 18 months in the score on the Clinical Dementia Rating–Sum of Boxes (CDR-SB; range, 0 to 18, with higher scores indicating greater impairment).[3] Read more here.

GLOBAL RANKING OF PHARMACEUTICAL COMPANIES

At the end of the year, specialized companies prepare rankings of companies' global turnover. We've included an interesting figure of the top 19 global pharmaceutical companies in 2021.

NEW GENE THERAPY FOR HEMOPHILIA

EMA has recommended granting a conditional marketing authorization in the European Union (EU) for Hemgenix (etranacogene dezaparvovec) for the treatment of severe and moderately severe hemophilia B in adults who do not have factor IX inhibitors. Haemophilia B is an inherited disorder characterized by an increased bleeding tendency due to a partial or complete deficiency of coagulation factor IX. The deficiency of factor IX is the result of mutations of the respective clotting factor gene. Prolonged bleeding episodes in patients with hemophilia B can lead to serious complications, such as bleeding into joints, muscles or internal organs, including the brain.



Hemophilia B is a rare debilitating disease affecting approximately 1 in 20,000 to 50,000 live male newborns.[4]

Continue reading here.

IN MEMORY OF LOUIS PASTEUR

Louis Pasteur was born in France on Dec 27, 1822. He was a young polymath when he embarked on a path of discovery with profound societal relevance. By the age of 40 years, he was a national hero and an international authority on microbiology, vaccines, and immunology. His germ theory of disease laid the foundation for hygiene and sanitation within public and global health. He developed the first vaccine against human rabies in 1885. Along with other great scientists of his time, Pasteur shaped scientific reasoning and communication for the better, creating a legacy that catalyzed progress in human health that has been sustained for the past 150 years. According to Pasteur, “In our century, science is the soul of the prosperity of nations and the living source of progress. Undoubtedly, the tiring daily discussions of politics seem to be our guide—empty appearances! — what really leads us forward are a few scientific discoveries and their applications.”[5] Read more here.

CORPORATE INVESTORS IN PRIMARY CARE

On July 21, 2022, Amazon announced plans to acquire One Medical — a primary care practice with nearly 200 locations serving more than 700,000 patients — for $3.9 billion. The deal, if approved, would represent Amazon's largest payment for a healthcare company to date. On September 5, 2022, CVS Health confirmed its acquisition of Signify Health, which offers in-home and traditional primary care, for around $8 billion.

These deals reflect a broader trend in the United States toward corporate investment in primary care, driven by an increasing focus on "total-cost value-based care"— a model in which healthcare providers are paid to manage the total cost of care for their patients and the size of-

each patient's capitated budget may be increased on the basis of the patient's health risks and the provider's performance on quality metrics. Though potentially beneficial for certain well-insured patients, the trend of corporate investment in primary care could threaten equitable access to care, raise healthcare costs, and reduce physicians' clinical autonomy. [6]

Read more here.

STATUE OF HENRIETTA LACKS WILL BE ERECTED IN VIRGINIA

In 1951, Henrietta Lacks, a young black mother in Baltimore, Maryland, began experiencing pain in her abdomen and abnormal bleeding. She was examined by gynecologists at Johns Hopkins Hospital, and they discovered a large mass on her cervix. Without informing her or asking for permission, doctors sent a sample of Mrs. Lacks' tumor to a lab for medical research before treating her for aggressive cervical cancer. At that time, it was common practice for doctors to harvest samples from their patients for further medical research.

Mrs. Lacks' cells proved to be a medical miracle, and after more than 70 years, a life-size bronze of Henrietta Lacks will be erected in her hometown of Roanoke, Virginia. [7]

Continue reading here.

COVID LESSONS FROM JAPAN

Through six waves of COVID-19 in Japan, the number of cases and deaths per capita has been significantly lower than in other G7 countries. This is despite having the world's oldest population and being densely packed. Yes, Japan has high vaccination rates, especially for older people, and masking is common.

But neither of these fully explains such vast differences. Deaths were low even before vaccines were available, and masks are common across Asia. Japan has sought to understand the spread and risks of the disease and apply that to minimizing deaths and hospitalizations while maintaining social and economic activities.

Trade-offs among these factors can be uneasy. Strong social pressure probably helped to boost protective measures, such as mask-wearing and minimized risky behaviors. Overall, the government quickly equipped its people with information to take protective action and avoided rigid prescriptions.[8]

Read more here.

NATURE'S BIGGEST STORIES OF 2022

Many journals take advantage of the year's end to synthesize the last twelve months of events in the articles they've published throughout the year. Here are what Nature has selected to feature as its biggest life science news stories for 2022:

- AI predicts protein structures
- Monkeypox goes global
- Omicron's offspring drive the pandemic

Read summaries of these key stories for 2022 by clicking this link.

AI DRUG DESIGN COULD BE USED AS CHEMICAL WEAPON

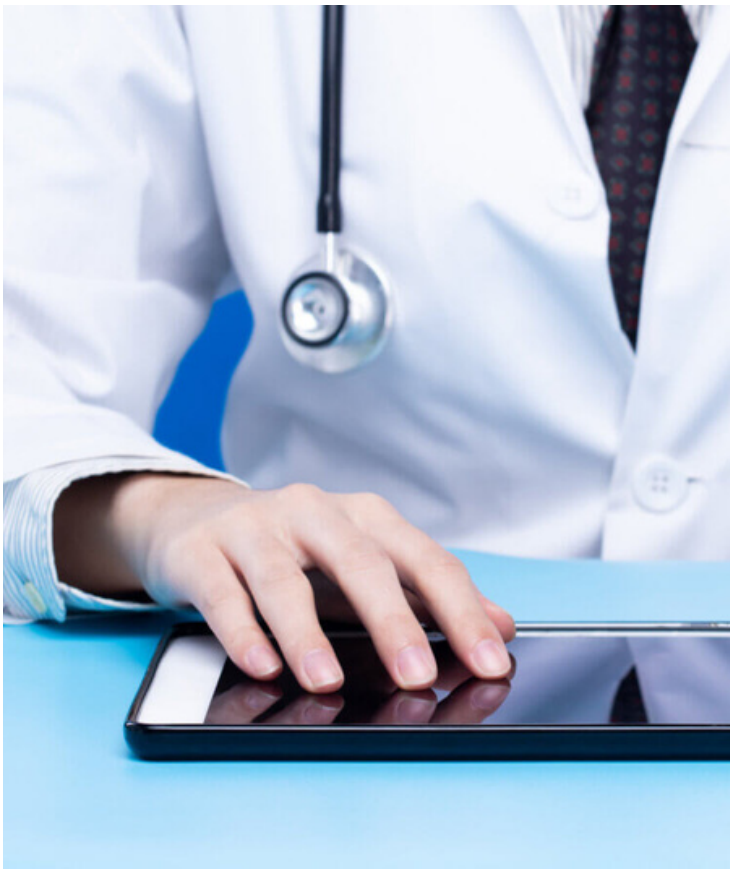
When a pharmaceutical company looked into whether its artificial-intelligence (AI) tools could be used to design biochemical weapons, the results horrified its researchers. Scientists used a machine-learning model that penalizes toxicity and inverted it to pursue compounds similar to the nerve agent VX, one of the most toxic chemical weapons ever created.

In less than six hours, the system designed VX and many other known chemical-warfare agents, as well as molecules predicted to be even more toxic. The frightening ease of the experiment should be a wake-up call for the AI drug-discovery community, argued Fabio Urbina and three colleagues in March.

"By going as close as we dared, we have still crossed a grey moral boundary," they write. "We can easily erase the thousands of molecules we created, but we cannot delete the knowledge of how to recreate them."[9]

Read more here.

THE LANCET AT 200: A START, BUT MORE TO DO



The year 2023 celebrates the 200th anniversary of The Lancet, a significant achievement for the publication. The first issue of the new year includes an editorial that both reflects on the past and emphasizes important commitments for the publication in the future. We have included a portion of the editorial below.

Thomas Wakley, a 27-year-old apothecary, surgeon, and sometime boxer, founded The Lancet in 1823. Wakley's intention was to publish reports of metropolitan hospital lectures, at the time a highly profitable activity for a small group of powerful physicians and surgeons in London. In addition to dismantling this private monopoly over medical knowledge, Wakley also hoped to provide "a correct description" of important clinical cases "a complete Chronicle of the current Literature".[10] Keep reading here.

ANNOUNCING THE GMDP ACADEMY

In its 7th year of outstanding stewardship, as a global center of education and training for Medicines Development professionals, **the IFAPP Academy is embarking on a landmark transformation**. While our goals remain unchanged, we recognize an opportunity to better achieve our mission of advancing all disciplines involved in pharmaceutical medicine / medicines development, to gain competence, seek professional identity, and harness the power of a sense of purpose.

With this transition, **we will reposition and rebrand to GMDP Academy** (Global Medicines Development Professional Academy), an education provider, enriched with a membership, with multiple educational offerings, CPD activities, and services. Our goal is to offer a unique, unparalleled platform for fostering continuing professional and personal growth while helping to establish and steer others down a career path for advancement.

The premise of a global, state-of-the-art, quality offering, with opportunity to learn from world-renowned experts and to network with todays and tomorrow's leaders from around the globe, backed by a dedicated team of acclaimed medicines development professionals, remains true to the GMDP Academy.

In the coming months, look out for a revamped and rebranded website, energized classroom settings and learning interfaces, and stimulating social media communications, culminating in a formal launch of the GMDP Academy later this year.

We value and expect your partnership, as we advance in the journey to consolidate medicines development as a new profession in healthcare.

Sincerely,
Honorio Silva, President
and
The IFAPP (GMDP) Academy Steering Committee:
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REFERENCES

1. Fauci responds to Musk's Twitter attack and rates world's COVID response. (2022, December 13). Nature. https://www.nature.com/articles/d41586-022-04432-7?utm_source=Nature+Briefing&utm_campaign=b0206d83a8-briefing-dy-20221214&utm_medium=email&utm_term=0_c9dfd39373-b0206d83a8-47677880
2. The Lancet Haematology. (2023). Strengthening cancer care in Europe. The Lancet Haematology, 10(1), e1. https://doi.org/10.1016/s2352-3026(22)00380-5
3. Van Dyck, C. H., Swanson, C. J., Aisen, P., Bateman, R. J., Chen, C., Gee, M., Kanekiyo, M., Li, D., Reyderman, L., Cohen, S., Froelich, L., Katayama, S., Sabbagh, M., Vellas, B., Watson, D., Dhadda, S., Irizarry, M., Kramer, L. D., & Iwatsubo, T. (2022). Lecanemab in Early Alzheimer's Disease. The New England Journal of Medicine, 388(1), 9–21. https://doi.org/10.1056/nejmoa2212948
4. First gene therapy to treat haemophilia B - European Medicines Agency. (2022, December 16). European Medicines Agency. https://www.ema.europa.eu/en/news/first-gene-therapy-treat-haemophilia-b
5. Lancet, N. (2022). Pasteur's legacy in 21st century medicine. The Lancet, 400(10369), 2157. https://doi.org/10.1016/s0140-6736(22)02573-9
6. Shah, S., Rooke-Ley, H., & Brown, E. C. F. (2023). Corporate Investors in Primary Care — Profits, Progress, and Pitfalls. The New England Journal of Medicine. https://doi.org/10.1056/nejmp2212841
7. Bailey, B. C. (2022, December 22). Statue of Henrietta Lacks will replace Robert E Lee. BBC News. https://www.bbc.com/news/world-us-canada-64059050?utm_source=Nature+Briefing&utm_campaign=22dd9c0dcf-briefing-dy-20221223&utm_medium=email&utm_term=0_c9dfd39373-22dd9c0dcf-47677880
8. COVID lessons from Japan: the right messaging empowers citizens. (2022, May 23). Nature. https://www.nature.com/articles/d41586-022-01385-9?utm_source=Nature+Briefing&utm_campaign=880196f532-briefing-dy-20230105&utm_medium=email&utm_term=0_c9dfd39373-880196f532-47677880
9. Urbina, F. L., Lentzos, F., Invernizzi, C. F., & Ekins, S. (2022). Dual use of artificial-intelligence-powered drug discovery. Nature Machine Intelligence, 4(3), 189–191. https://doi.org/10.1038/s42256-022-00465-9
10. L. (2023). The Lancet at 200: a start, but more to do. The Lancet, 401(10370), 1. https://doi.org/10.1016/s0140-6736(22)02586-7

Thanks for reading!

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