GMDP academy
ISSUE 27 • JUNE 13, 2023

PROFESSIONAL IDENTITY AND MEDICINES DEVELOPMENT: ACADEMY ALUMNA REFLECTIONS

Do you know your why? Have you defined your own Professional Identity? This essay continues our series on Professional Identity and Medicines Development. Today, we hear from a successful graduate of the Academy's 2022 cohort, Kelly Gordon. For this essay, Kelly was asked to "**Discuss Professional Identity and the Sense of Purpose in Medicines Development and their relevance for professionals involved in the field**." Our students make exceptional contributions to our learning community every day, and this is no exception. Thank you to Kelly for allowing the Academy to feature your insights.
Continue to page 2 to read a portion of her essay.

TABLE OF CONTENTS

PROFESSIONAL IDENTITY AND MEDICINES DEVELOPMENT: INSIGHTS FROM ACADEMY ALUMNA

Ultimately, it boils down to a person's individual unique experiences that help you develop and determine what Professional Identity means to you. These experiences allow you to cultivate your own Professional Identity over time. Professional Identity can change and evolve as you grow in your career. And you may need to redefine it when you are in a position that no longer fits your Professional Identity. Jill Donohue said, "To find meaning in your work, sometimes you need to change how you think about it." [1]

Professional Identity can change as you move into new roles throughout your career including leadership roles. Every leader should define their Professional Identity [2]. This helps us describe our "why" and share our individual brand with those we work with. As a leader, influence is crucial in our job. In order to be influential in our business we have to ensure we have a clear picture of our own brand [2]. Especially in an extremely competitive marketplace, leaders want to have the right team members working alongside them.

Everyone wants to have a sense of purpose. It is widely known that companies will perform better when they have a clear sense of purpose [3]. Employees are more engaged and believe in the "north star" described by their leadership. The engagement ultimately leads to improved performance and overall satisfaction in their job. Rebecca Henderson said it best, "The sense of being part of something greater than yourself can lead to high levels of engagement [3]."

Kelly Gordon graduated as a Pharmacist from The Medical University of South Carolina in 2009. She completed a PGY-1 residency and worked for several years in the clinical setting prior to joining Boehringer Ingelheim in 2015. She is currently a Senior Associate Director in Clinical Development & Medical Affairs, Specialty Care where she most recently launched a medication for a rare disease in dermatology. She leverages her knowledge from the Academy in preparation for future upcoming launches.

Click here to read her complete essay.

EMA RECOMMENDS BIMERVAX AS COVID-19 BOOSTER VACCINE

EMA's human medicines committee (CHMP) has recommended authorizing the COVID-19 vaccine Bimervax (previously COVID-19 Vaccine HIPRA) as a booster in people aged 16 years and above who have been vaccinated with an mRNA COVID-19 vaccine. Bimervax, developed by HIPRA Human Health S.L.U., contains a protein produced in the laboratory that consists of part of the SARS-CoV-2 spike protein from the Alpha and Beta virus variants

The CHMP concluded that sufficiently robust data on the quality, safety and immunogenicity of the vaccine are now available to recommend its marketing authorization in the EU.

The CHMP concluded that a booster dose of Bimervax is expected to be at least as effective as Comirnaty at restoring protection against COVID-19 in people aged 16 years and older. The safety profile of Bimervax is comparable to that of other COVID-19 vaccines.[4] Continue reading here.

PREVENTING LONG COVID

Do vaccination and nirmatrelvir prevent post–COVID-19 condition ("long COVID")? Two recent reports provide some answers to this question.

In a meta-analysis of 41 studies that involved 861,000 patients, researchers identified demographic and other factors associated with significant excess risk for long COVID in adults: female sex; older age; body-mass index (BMI), ≥30 kg/m2; current smoking; comorbidities (e.g., asthma, diabetes, heart disease, immunosuppression); and previous hospitalization for COVID-19. In contrast, prior two-dose vaccination for COVID-19 was associated with significantly lower risk for long COVID (by 43%).

Nirmatrelvir was associated with lower risk for long COVID in people who were unvaccinated, vaccinated, or boosted and in people with either primary infections or reinfections. Read more here.[5]

ECONOMIC EVALUATIONS' IMPACT ON DRUG PRICING

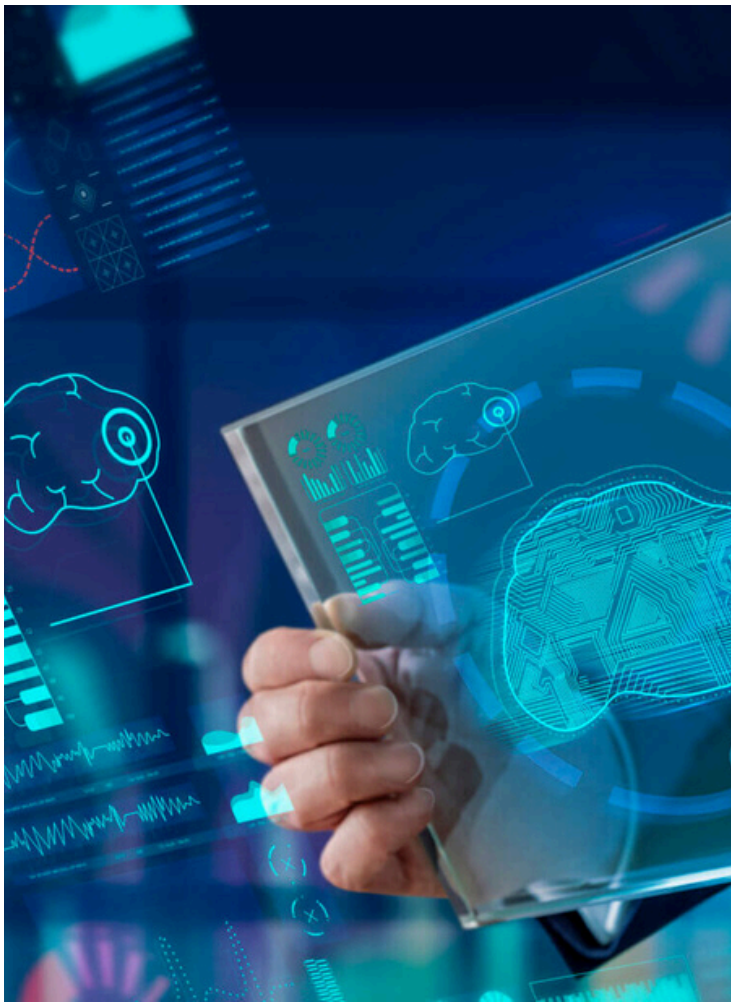
A recent analysis has uncovered insights into the pricing negotiation process for medicines in Italy. According to the study, the average Incremental Cost Effectiveness Ratio (ICER) following negotiations with the Drug Agency (AIFA) stands at €33,004 per Quality Adjusted Life Year (QALY). The analysis, conducted by experts from AIFA and the Centre for Health Economics in York, examined 48 dossiers submitted between October 2016 and January 2021, using beta-based regression analyses to assess the effect of ICER and other variables on negotiation outcomes.

The study found “the ICER before negotiation to be one of the variables with a major impact on [the outcome of price negotiation]

and the only one with a statistically significant impact when its value was ≥ €40,000/QALY.” [6]

Keep reading here.

ARTIFICIAL INTELLIGENCE IN MEDICINE



Applying Artificial Intelligence to medicine presents unique challenges. AI in healthcare necessitates stringent ethical, governance, and regulatory considerations in the design, implementation, and integration of AI applications and systems. Just like any medical technology, new AI applications must adhere to rigorous testing standards to ensure both efficacy and safety.

According to an article from the New England Journal of Medicine, "Medicine is much different from other areas where AI is being applied. AI enables new discoveries and improved processes in the entire health care continuum; ethical, governance, and regulatory considerations are critical in the design, implementation, and integration of every component of the AI applications and systems." [7]

Read more here.

THE CRIMINALIZATION OF SUICIDE

Suicidality is on the rise. Roughly 703,000 people die by suicide every year, and for every person who ends their life by suicide, another 20 people attempt to do so. Given these alarming statistics, it would seem that evidence-based treatment and care are the only humane approaches to this global health crisis. However, at least 20 countries engage in the criminalization of suicide in that they punish death by suicide and attempted suicide by imprisonment and/or financial penalties. These punishments and the legislations associated with them are due in large part to two very common misconceptions: that decriminalizing suicide is tantamount to accepting it, and that legislative punishment of suicide is a deterrent to it.

“Treatment of people in crisis and who report ideas about wanting to end their lives remains far from optimal—even in countries that have abandoned legislation against suicide and attempted suicide...More humane approaches should be universal." [8]

Read more here.

FDA NEWS: QSAR MODELS FOR PREDICTING BLOOD BRAIN BARRIER PERMEABILITY

In FDA news, Quantitative Structure-Activity Relationship (QSAR) models have emerged as a vital tool in regulatory reviews, offering a swift evaluation of the toxicological and pharmacological properties of chemical compounds based solely on their structural features.

These models are increasingly employed to expedite experimental investigations into the potential effects of newly identified drugs of abuse and aid in emergency scheduling. QSAR models offer regulatory agencies a practical solution when empirical data is scarce or unavailable, allowing them to assess the toxicological/pharmacological potential of substances at endpoints crucial for regulatory decision-making.

A recent article from the FDA explores the growing importance of QSAR models in regulatory contexts, highlighting their utility and significance in addressing knowledge gaps and facilitating efficient risk assessment processes. [9]

Continue reading here.

THE IMPACT OF SEX AND GENDER ON NEUROLOGICAL DISEASES

The understanding of sex and gender differences in neuroscience and neurology holds promise for earlier diagnosis, more reliable treatment, and effective disease management, thereby reducing the impact on individuals, families, societies, and economies.

"Sex is associated with differences in the risks for and prevalence of several neurological disorders and responses to some treatments; gender can affect diagnosis and prognosis, for instance if cultural norms mean that people are reluctant to seek health care or if health-care professionals have preconceived ideas of who is more likely to have a disease." Despite this, the consideration of sex and gender in brain research remains limited.

A white paper titled "Sex, Gender, and the Brain: Towards an Inclusive Research Agenda" advocates for increased investment in studying the effects of sex and gender on neurological diseases, citing potential benefits for individuals and economies. [10]

Continue reading here.

CIOMS UPDATES CUMULATIVE GLOSSARY

CIOMS is pleased to advise that the organization just published an update of the CIOMS Cumulative Glossary with a focus on Pharmacovigilance. This publication has been very successful, with more than 6500 downloads since its launch in March 2021. Version 2.1 newly includes the definitions from the CIOMS Working Group report on clinical research in resource-limited settings, as well as three definitions added by the Glossary Advisory Board.

The Glossary is available for free download. It is a great free resource for anyone working in pharmacovigilance and related fields or interested in the history and evolution of pharmacovigilance.

You can access the glossary here.

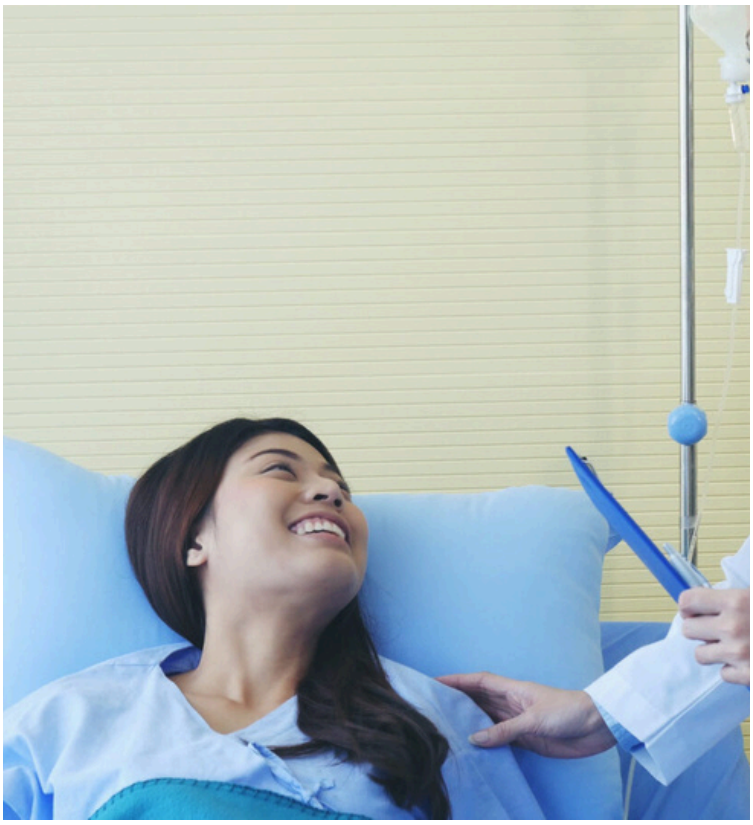
EMA'S MOST RECENT NEWSLETTER NOW AVAILABLE

The European Medicines Agency has published its most recent monthly newsletter. By subscribing to the EMA newsletter, you receive key information relating to medicines for human use. Have you ever wondered how the EMA selects the information to be published? According to the newsletter, “information is selected based on recommendations from consulted patients, consumers, and healthcare professionals.” [11]

This is a very useful resource for patients, consumers, and healthcare professionals.

Click here to access the most recent newsletter.

GLOBAL ACCESS TO NEW MEDICINES REPORT INDICATES GLOBAL PATIENT ACCESS CHALLENGES



A new report from PhRMA, the Global Access to New Medicines Report, highlights significant disparities in the availability and public reimbursement of new medicines among G20 countries. The study analyzed 648 new medicines approved by the FDA, EMA, or Japan’s PMDA between 2005 and 2021. The United States had the highest percentage of new drugs launched and publicly reimbursed, with 85% of drugs available and covered by public health insurance. This advantage can be attributed to the U.S. being a primary destination for regulatory approval and having a more streamlined reimbursement process. [12]

You can access the report here. Click here to read a full summary.

REFERENCES

1. The Power of Purpose video by Jill Donohue
2. Gbenga Ogunjumi. 5 REASONS YOU SHOULD DEFINE YOUR PROFESSIONAL IDENTITY BY YOURSELF. 5 REASONS YOU SHOULD DEFINE YOUR PROFESSIONAL IDENTITY BY YOURSELF (linkedin.com)
3. The Business Case for Purpose. Harvard Business Review. The Business Case for Purpose – SPONSOR CONTENT FROM EY (hbr.org)
4. Ema. (2023, March 31). EMA recommends approval of Bimervax as a COVID-19 booster vaccine – European Medicines Agency. European Medicines Agency. https://www.ema.europa.eu/en/news/ema-recommends-approval-bimervax-covid-19-booster-vaccine
5. Facp, P. S. M. M. M. (2023). Preventing “Long COVID.” www.jwatch.org. https://doi.org/10.1056/nejm-jw.NA55957
6. Russo, P., Zanuzzi, M. G., Carletto, A., Sammarco, A., Romano, F., & Manca, A. (2022). Role of Economic Evaluations on Pricing of Medicines Reimbursed by the Italian National Health Service. PharmacoEconomics, 41(1), 107–117. https://doi.org/10.1007/s40273-022-01215-w
7. Beam, A. L., Drazen, J. M., Kohane, I. S., Leong, T., Manrai, A. K., & Rubin, E. J. (2023). Artificial Intelligence in Medicine. The New England Journal of Medicine, 388(13), 1220–1221. https://doi.org/10.1056/nejme2206291
8. Lancet. (2023). Punishing the tortured: criminalisation of suicide. The Lancet, 401(10384), 1241. https://doi.org/10.1016/s0140-6736(23)00764-x
9. https://www.fda.gov/drugs/regulatory-science-action/new-developments-regulatory-qsar-modeling-new-qsar-model-predicting-blood-brain-barrier-permeability
10. Neurology, L. (2023). Sex, gender, and the cost of neurological disorders. Lancet Neurology, 22(5), 367. https://doi.org/10.1016/s1474-4422(23)00120-5
11. EMA May 2023 newsletter
12. Global Access to New Medicines Report. (n.d.). PhRMA. https://phrma.org/resource-center/Topics/Access-to-Medicines/Global-Access-to-New-Medicines-Report

Thanks for reading!

The GMDP Academy Newsletter is published bi-monthly and is compiled by the following:

Medical Editor: Domenico Criscuolo

Media Manager: Whitney English

Editorial Board: Pravin Chopra, Jacob Coots, Honorio Silva, Peter Stonier

Operations Office: Amanda Schmitt, Gustavo Silva, Kiet Vo

CONTACT US:

420 Lexington Ave. Ste. 300
New York, NY 10170

(332) 333-2438