GMDP academy
ISSUE 32 • AUGUST 24, 2023

PROFESSIONAL IDENTITY AND MEDICINES DEVELOPMENT: INSIGHTS FROM DR. TOSHIYA SUGINO, ACADEMY ALUMNI

As we proceed with our exploration of Professional Identity and its connection to Medicines Development, we are delighted to introduce the release of an excellent essay by Dr. Toshiya Sugino, a graduate of our 2022 cohort. Dr. Sugino was prompted to "**Discuss Professional Identity and the Sense of Purpose in Medicines Development and their relevance for professionals involved in the field**." Read more on page 2.

TABLE OF CONTENTS

PROFESSIONAL IDENTITY AND MEDICINES DEVELOPMENT: INSIGHTS FROM ACADEMY ALUMNI

Considering Professional Identity in Medicines Development, it is important to think about the purpose of pharmaceutical medicine /Medicines Development. Our ultimate purpose as Medical Affairs professionals is to develop beneficial and safe medicinal products for patients and the public. To achieve this, the functions such as clinical research, safety, clinical operations, regulatory and Medical Affairs are essential in Medicines Development.

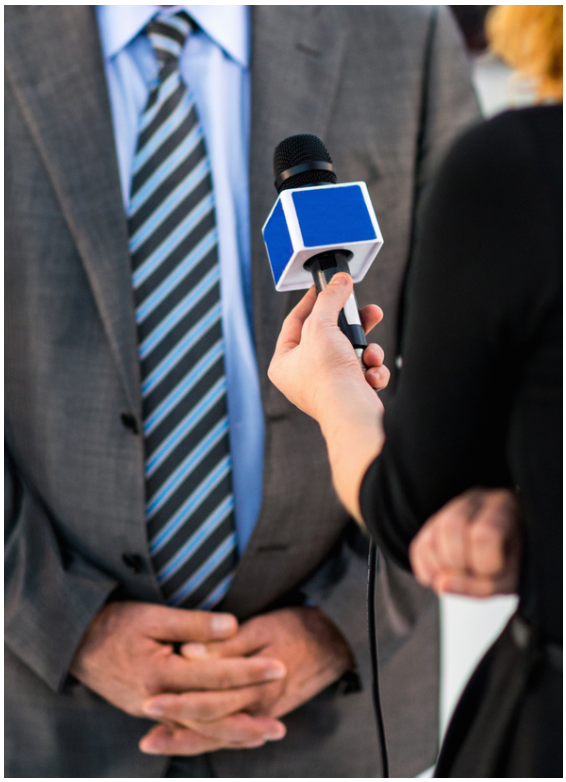
Focusing on the roles and responsibilities of Medical Affairs professionals in the pharmaceutical industry, the functions of Medicines Development have been reinvented, and Medical Affairs are constantly required to update their knowledges and skills and to quickly adjust to change to meet greater demands and expectations from the medical community to include therapeutic specialties, patient groups, regulatory authorities, and the pharmaceutical industry. Due to rapidly changing needs of the customer as well as changes in the external environment, Medical Affairs needs to efficiently change and adapt from a traditional, supportive function to a more proactive role. To do it, it is essential for Medical Affairs professionals to have a strong sense of purpose which becomes a core driver of strategy and decision-making and leads to the ability to deliver revenue growth and drive successful innovation and transformation. The Academy's program has provided me with not only diverse topics related to Medicines Development but also an understanding of the principles of health economics, marketing, as well as drug discovery and development. I believe that the Academy programs will be involved in the development of my Professional Identity and will help me transform and develop new capabilities.

Toshiya Sugino, MD, PhD is the Senior Medical Manager for Pfizer, Japan in Tokyo.

Click here to read his complete essay.

INTERVIEWS WITH THE ACADEMY: DR. HONORIO SILVA ON WHAT SETS THE ACADEMY APART

In our continued commitment to provide our readers with comprehensive and insightful content, we excitedly introduce our latest featured series: "Interviews with the Academy." The newest addition to our social media and newsletter content will feature segmented interviews from renowned industry experts, visionaries, and thought leaders who are dedicated to the continued advancement of Medical Affairs and Medicines Development.



In our inaugural interview, we had the privilege to sit down with Dr. Honorio Silva, GMDP Academy President. The first featured segment gives readers an opportunity to hear from Dr. Silva himself about his passion for the Academy, and what makes this organization truly unique. Watch the first *Interviews with the Academy* segment here.

APPLICATIONS NOW AVAILABLE FOR WORLD-CLASS EDUCATION IN MEDICINES DEVELOPMENT

The GMDP Academy, in collaboration with King's College London, is pleased to accept applications for the 2024 cohort of the highly acclaimed Certification in Medicines Development (CMD) program.

Don't miss your chance to become part of a truly unique educational journey in Medicines Development! Join fellow professionals from around the world and advance your career with the 2024 GMDP Academy-King's College London Certification in Medicines Development Program .

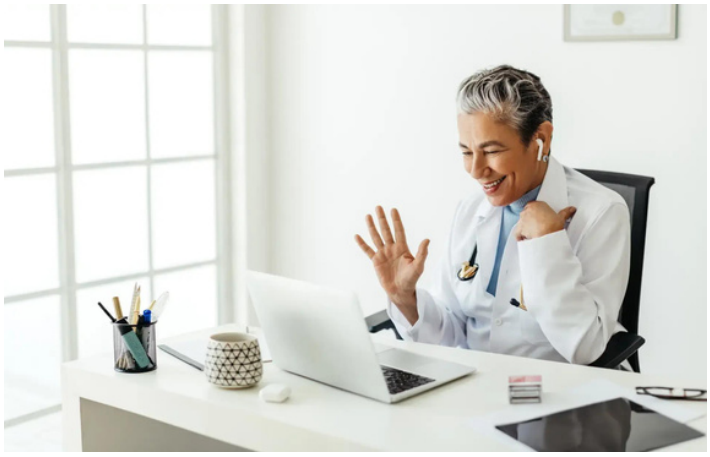
Group rates are available for sponsoring organizations. For more information contact admissions@gmdpacademy.org.

Apply Today

TELEHEALTH TRENDS IN THE UNITED STATES

Early in the pandemic, the rapid adoption of telehealth in the United States offset some of the declines in doctor visits during lockdowns and requirements in hospitals and medical practices. Telehealth visits in the United States accounted for less than 1% of visits prior to the pandemic, rose to 26% in April 2020 at the height of the pandemic, and declined to 5% over the last half of 2022.

Slight increases in the use of telehealth in the United States can be seen during times of increased COVID-19 activity (i.e., December 2020, January 2022) as phone or video visits, particularly for those suspected of having COVID-19, as telehealth visits can be used to reduce the spread of the virus.



As of the end of 2022, 43 states required commercial insurers to reimburse for-telehealth, although only 24 states have laws addressing payment parity between face-to-face and telehealth visits.[1]

You can read the IQVIA 2023 report on the use of medicines in the US by clicking here. Access the IQVIA website and additional 2023 reports here.

PREPARING FOR EFFECTIVE TREATMENT OF ALZHEIMER'S DISEASE

Recent advancements in Alzheimer's disease research have yielded breakthroughs in biomarkers, diagnostic criteria, and disease-modifying trials, culminating in the approval of drugs capable of eliminating amyloid plaques from the brain. While lecanemab gained approval from the US FDA and is expected to receive conventional approval soon, the clinical benefits of aducanumab remain uncertain, with ongoing trials focusing on cognitive decline. The implementation of these treatments for Alzheimer's disease research requires meticulous preparation within healthcare systems to ensure safe delivery and equitable access, particularly in regions with aging populations, necessitating the establishment of protocols and guidelines for effective management.[2] Continue reading here.

AI'S POTENTIAL IN THE TREATMENT OF CANCER

The rapid evolution of artificial intelligence (AI) since its inception has surpassed expectations, impacting daily life, and work, and demonstrating significant potential for the advancement of modern medicine. ChatGPT, a sophisticated language model, stands out as the fastest-growing internet application, amassing over a billion subscribers since its November 2022 release, with 100 million monthly active users. Amid privacy and security concerns, the potential of AI to enhance oncology care is investigated. Geoffrey Hinton, a prominent AI figure, resigned from Google to voice apprehensions about AI's risks, sparking discussions about AI's potential autonomy and regulatory needs.

The article reflects on AI's potential as a human potential enhancer while emphasizing the necessity for robust regulation to manage its rapid advances. [3]

Keep reading here.

AUSTRALIA TAKES A STRICTER STANCE ON E-CIGARETTES AND VAPING

Australia's historically moderate approach to e-cigarette usage shifts as Health Minister Mark Butler highlights its evolution from a therapeutic aid to a youth-targeted recreational product. The Labor Federal Government, following public input, is proposing rigorous regulations on e-cigarettes, addressing importation, content, and packaging. While nicotine-containing e-liquids are only legally accessible through prescriptions, enforcement against illegal sales has been lacking. The Labor Government plans to collaborate with regional authorities to combat the growing illegal vaping market, curbing non-prescription imports and enforcing higher quality standards. Measures encompass flavor restrictions, pharmaceutical-like packaging, reduced nicotine concentrations, and a ban on disposable vapes.[4]

Continue reading here.

ICH PUBLISHES THIRD REVISION TO ICH E6 GUIDELINE

The revised edition of the ICH E6 guideline, which outlines Good Clinical Practice (GCP) standards for human pharmaceutical trials, has been made available for public consultation by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. This marks the third iteration of the guideline, highlighting the rapid pace of advancement in the field of Medicines Development.

Good Clinical Practice (GCP) serves as a worldwide benchmark for the ethical, scientific, and quality aspects of conducting trials involving human subjects.

Adhering to this standard in clinical trials ensures the protection of participants' rights, safety, and well-being.[5] Interested parties are encouraged to provide their feedback and recommendations by **September 26, 2023**. Keep reading here.

CLOSING THE VACCINE-COVERAGE GAP FOR UNINSURED ADULTS

The effectiveness of the U.S. Covid-19 vaccination strategy, focused on the rapid and widespread distribution of free Covid-19 vaccines, is evident in the administration of over 670 million vaccine doses to more than 270 million Americans by the conclusion of the national public health emergency. However, as the nation approaches the upcoming fall season, a new challenge emerges as Covid-19 vaccines transition into the commercial market, potentially limiting access for adults without health insurance. In alignment with its ongoing commitment to ensuring fair access to Covid-19 vaccines, the Biden administration took a significant step in April 2023 by introducing the Health and Human Services Bridge Access Program for Covid-19 Vaccines and Treatments.[6]

Continue reading here.

REFERENCES

1. The Use of Medicines in the U.S. 2023. (n.d.). IQVIA. https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us-2023
2. Neurology, N. L. (2023). Treatment for Alzheimer's disease: time to get ready. Lancet Neurology, 22(6), 455. https://doi.org/10.1016/s1474-4422(23)00167-9
3. Oncology, N. L. (2023). Can artificial intelligence improve cancer care? Lancet Oncology, 24(6), 577. https://doi.org/10.1016/s1470-2045(23)00240-1
4. Kirby, T. (2023). Australia to introduce sweeping e-cigarette regulations. The Lancet, 401(10388), 1557. https://doi.org/10.1016/s0140-6736(23)00954-6
5. Research, C. F. D. E. A. (2023). E6(R3) GOOD CLINICAL PRACTICE (GCP). U.S. Food And Drug Administration. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e6r3-good-clinical-practice-gcp
6. Wallender, E., Peacock, G., Wharton, M., & Walensky, R. P. (2023). Uninsured and Not Immune — Closing the Vaccine-Coverage Gap for Adults. The New England Journal of Medicine, 389(3), 193–195. https://doi.org/10.1056/nejmp2306200

Thanks for reading!

The GMDP Academy Newsletter is published twice 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, Kit Vale

CONTACT US:

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

(332) 333-2438