



PROFESSIONAL IDENTITY AND MEDICINES DEVELOPMENT: INSIGHTS FROM DR. DIANA GRANGEIA, ACADEMY ALUMNA

As we proceed with our exploration of Professional Identity and its connection to Medicines Development, we are pleased to introduce the release of an excellent essay by Dr. Diana Grangeia, a graduate of our 2022 cohort. Dr. Grangeia 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.

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PROFESSIONAL IDENTITY AND MEDICINES DEVELOPMENT: INSIGHTS FROM ACADEMY ALUMNA



Our individual purpose is what drives our passion and makes us act in a very authentic way. To find it we must be curious and courageous enough to not only make some questions but most importantly to listen to our own answers [1].

From my perspective, when we talk about Medicines Development, we are talking about impacting society and its most vulnerable people: patients. In this field, the aim of companies is to develop high quality products that are highly effective and safe, so patients have better care, healthcare providers have better tools, and the healthcare system has better results. This industry requires time, financial investment, high-performance teams, and a lot of regulation. This way, it is of extreme importance that people come to Medicines Development with skills and technical knowledge along with a strong purpose: to deliver the best products, consume less time, attract investment, create value for customers and retain talent.

I believe that with a purpose-driven mentality, companies and employees will be able to face this changing world by adapting their professions, eventually even their Professional Identities, so they do not compromise what matters the most: the mission towards patients!



Diana Marques Grangeia is a 32-year-old Medical Doctor who, after 5 years in the Portuguese National Healthcare System, gave up Pathology Residency to unleash her potential on Business Management and Medicines Development. Since 2019 in the Pharmaceutical Industry working on Medical Affairs, Diana is currently Medical Manager at Novartis, keeping her mission toward patients and Society alive. Diana leads as a team player, with resilience and ambition in her DNA, along with the power to believe that (pretty much!) anything is possible!

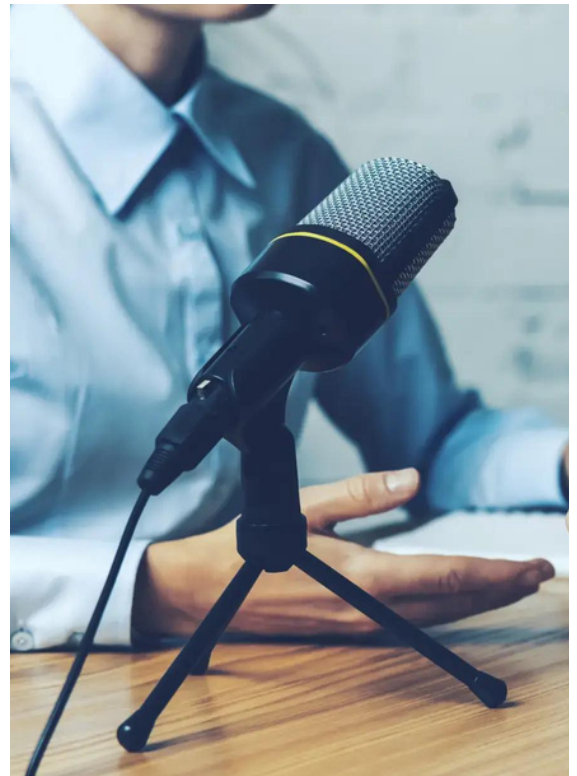
Click [here](#) to read her complete essay.

GUIDING THE PATH TO MEDICINES DEVELOPMENT: WISDOM FROM THE ACADEMY PRESIDENT

As the pharmaceutical landscape continues to evolve, stepping into the realm of developing life-saving medicines can be both exhilarating and daunting for newcomers.

In our latest Interviews with the Academy segment, we have the privilege of hearing some profound insights from Dr. Honorio Silva about his own journey in the field, and what he'd like those just starting in their journey to know.

Watch the latest *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](#)

CDER & GLOBAL REGULATORY COLLABORATION

The FDA and the EMA have successfully completed the first collaborative assessment of a proposed post-approval change for a crucial oncology biologic, with the Japanese PMDA as an observer. This collaborative effort involved the FDA and EMA reviewing and approving a proposal to incorporate new manufacturing and quality control sites. The aim of this collaboration is to ensure a consistent supply of the medicine. This achievement is part of an international pilot program under the International Coalition of Medicines Regulatory Authorities (ICMRA) Pharmaceutical Quality Knowledge Management System (PQKMS) initiative. The program seeks to bring together regulatory authorities to enhance industry quality management, ensuring a dependable supply of essential medicines for patients.



This collaboration follows a broader trend of global regulatory bodies working together to tackle challenges related to drug availability. Manufacturing changes are often made by drug manufacturers to modernize processes and facilities and overcome supply chain obstacles.²

Read more [here](#).

CIOMS JUNE NEWSLETTER: UPDATES AND REMEMBRANCE



The CIOMS June 2023 Newsletter is now available. Good progress has been made in the second quarter of 2023. Three CIOMS Working Group reports have been released for public consultation—two of which are still open for comments—and CIOMS has been represented at various international events.

In this issue, we remember our colleague of many years Sev Fluss, former Chief of the WHO Health Legislation Unit, who passed away at the end of May.

You may also wish to take a look at our roundup of global news related to the CIOMS areas of work, including information about various draft regulatory guidance documents that have been published for comments. Read newsletter #42 [here](#).

ETHICS AND THE DEATH PENALTY IN MEDICINE

In April 2023, during the 52nd session of the Human Rights Council, the UN High Commissioner for Human Rights, Volker Türk, strongly criticized the death penalty as an outdated and inhumane practice that contradicts modern values. The historical involvement of physicians in executions has given the practice an aura of legitimacy, but it fundamentally clashes with the ethical principles of their profession. Amnesty International's report revealed a troubling rise in official executions globally, with China, Iran, Saudi Arabia, Egypt, and the USA among the top executioners, often linked to authoritarian regimes and the suppression of political dissent, drug offenses, and LGBTQ+ identities. "Officially documented executions increased by 53%, from 579 in 2021 to 883 in 2022.



The world's most prolific executioners in 2022 were: China (thousands), Iran (576), Saudi Arabia (196), Egypt (56), and the USA (18). 93% of global executions, excluding China, were carried out in the Middle East and north Africa.³ Keep reading [here](#).

STRATEGIES FOR THE EVOLVING LANDSCAPE OF COVID-19 VACCINES FOR EMERGING VARIANTS



International regulators convened to discuss the evolving landscape of COVID-19 vaccines and the necessity to update their formulations based on emerging evidence about SARS-CoV-2 variants and lessons drawn from prior vaccine adaptations. Co-led by the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA), the workshop, hosted by the International Coalition of Medicines Regulatory Authorities (ICMRA), transpired on May 8, 2023.

While the existing authorized COVID-19 vaccines remain effective against severe illness and death, their protection against infection diminishes over time and with the emergence of new variants. The workshop's participants reviewed scientific evidence encompassing epidemiology, seroprevalence, vaccine performance, and regulatory factors associated with adjusting authorized or new COVID-19 vaccines to counter emerging coronavirus variants. Continue reading [here](#).⁴

ASSESSING GLOBAL EFFORTS TO COMBAT ANTIMICROBIAL RESISTANCE

This article delves into the imperative task of understanding and evaluating global efforts to combat antimicrobial resistance, which poses a significant threat at national, regional, and global levels. National Action Plans (NAPs) stand as pivotal instruments guiding antimicrobial resistance governance within nations, yet a comprehensive analysis of these plans has been notably absent.

Employing a meticulous governance framework, this study undertook a systematic review of publicly available NAPs from 114 countries, scrutinizing them across 18 domains and 54 indicators spanning policy design, implementation tools, and monitoring and evaluation.



The research incorporated data from diverse sources and involved an exhaustive process of assessment, ranking, and analysis, revealing substantial variations in governance scores and highlighting key areas where improvements are needed to address this critical global health challenge effectively. Read more [here](#).⁵

IQVIA REPORT: CLINICAL TRIAL SUBJECTS NUMBER DROPS DUE TO DECLINE IN COVID-19 ENROLLMENT



The Global Trends in R&D report by IQVIA reveals a noteworthy trend in clinical trials participation over the past four years. In 2021, the number of participants surged to nearly 4 million, remaining impressively high at 1.9 million in 2022. The most substantial growth has been observed in infectious disease trials. Excluding COVID-19 and Ebola studies, the number of subjects reached nearly 600,000 in 2022, showing a remarkable increase from the 125,000 recorded in 2018. However, it's essential to note that there was a decline in clinical trial enrollment attributed to the drop in COVID-19 trials. In 2020, these trials involved a staggering 1 million participants. While an additional 2.4 million individuals joined clinical trials in 2021, the numbers decreased, with more than 330,000 participants in 2022.⁶

Continue reading [here](#).

"The Fight against Cancer –
Vaccines or
Immunotherapeutics?"

September 25, 2023
8:00 AM - 9:00 AM EST



Professor Gilberto Filaci

Immunologist
University of Genova, Italy



Dr. Otfried Kistner

Senior Consultant &
Independent Vaccine Expert,
Vienna

In the last twenty years, the medical and scientific communities have made remarkable strides in understanding the critical role of our immune system, specifically the role it plays in chronic diseases such as asthma, diabetes, cancer, etc. This understanding has allowed us not only to understand the causes of such diseases but has also stimulated research into therapies that may positively impact patient outcomes. In this webinar, Dr. Otfried Kistner and Professor Gilberto Filaci will provide an in-depth discussion of the most promising approaches to cancer treatment currently being explored in the field.

Learning Objectives

1. Present an up-to-date overview of ongoing research endeavors focused on the development and discovery of a cancer vaccine.
2. Furnish the current status of ongoing investigations in this field.
3. Evaluate the merits and limitations inherent in research initiatives currently in progress.

[Register Now](#)

REFERENCES

1. How To Identify and Work with Your Core Purpose (worldclasseminars.com) (consulted 16/11/2022)
2. Research, C. F. D. E. A. (2023). CDER collaborates with global regulators on pharmaceutical quality assessments and inspections. U.S. Food And Drug Administration. <https://www.fda.gov/drugs/news-events-human-drugs/cder-collaborates-global-regulators-pharmaceutical-quality-assessments-and-inspections>
3. 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>
4. Ema. (2023, May 30). Global regulators agree on way forward to adapt COVID-19 vaccines emerging variants – European Medicines Agency. European Medicines Agency. <https://www.ema.europa.eu/en/news/global-regulators-agree-way-forward-adapt-covid-19-vaccines-emerging-variants>
5. Patel, J., Harant, A., Fernandes, G., Mwamelo, A. J., Hein, W., Dekker, D., & Sridhar, D. (2023). Measuring the global response to antimicrobial resistance, 2020–21: a systematic governance analysis of 114 countries. *Lancet Infectious Diseases*, 23(6), 706–718. [https://doi.org/10.1016/s1473-3099\(22\)00796-4](https://doi.org/10.1016/s1473-3099(22)00796-4)
6. Global Trends in R&D 2023. (n.d.). IQVIA. <https://www.iqvia.com/insights/the-iqvia-institute/reports/global-trends-in-r-and-d-2023>

Thanks for reading!

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