



PROFESSIONAL IDENTITY AND MEDICINES DEVELOPMENT: LESSONS FROM OUR ALUMNI

BY DR. RACHEL LAWSON

We continue with our Professional Identity and Medicines Development series. We are excited to share the perspectives of our students and alumni. Below is an essay written by Dr. Rachel Lawson. The Academy extends its sincerest thanks to Dr. Lawson for her contributions to our community.

Dr. Lawson responded to the prompt, "Characterize Professional Identity in Medicines Development and the need for Professional Identity for professionals involved in the field." See *page 2*.

TABLE OF CONTENTS

Professional Identity and Medicines Development • P. 2

Polio Eradication: Falling at the Final Hurdle? • P. 3

The CDC on Antimicrobial Resistance • P. 3

The Sputnik V Vaccine • P. 4

Oral Antivirals for Covid-19 • P. 4

EMA and AI-Powered Intelligence • P. 5

New Co-Chairs Elected for EMA Working Parties • P. 5

Expand Your Career with IFAPP Academy Training • P. 6

"...Experiences and learnings shape one's professional identity. Interactions with fellow students, mentors and instructors are instrumental whilst studying. Vocationally, interactions with colleagues and stakeholders (including healthcare workers) are instrumental (Weaver et al., 2011).¹As professional identities form, the person starts to think, to act and feel like the professional they aim to become (Cruess et al., 2014).² In medicines development, an initial professional identity as a physician will further evolve as the environment and socialization process are different. The individual will work with a different community compared to that of the pure clinician. The roles the individual plays will differ and, whilst the patient remains at the centre of their thoughts and actions, the patient may represent a group or community rather than a distinct individual. This is demonstrated in the conflicting philosophy of clinical trials and standard clinical care (Cooper, 2012).³ A strong professional identity helps reframe the conflicts between old identities as physicians and new, as drug developers.

Development of a professional identity requires one to internalise the characteristics, values, and norms of the profession (Jarvis-Selinger et al., 2012).⁴ The development of values and adoption of behaviours specific to one's role in medicines development will reflect the different functions performed. Medical affairs professionals have diverse functions and require a working knowledge of all aspects of drug development. Formal educational courses not only impart the necessary knowledge, but through interactions with fellow students, the course leaders, and lecturers, create experiences and interactions crucial to socialization."



Rachel's interest in Medicines Development dates back to her undergraduate days and prompted her to take up her first industry position as a development chemist at GlaxoSmithKline whilst studying for her undergraduate degree. Following her PhD and working as a research fellow in the UK and USA, Rachel initially moved into clinical research in the National Health Service before returning to industry in clinical operations. Five years ago, she had the opportunity to join Sanofi in Medical Affairs. She enjoys the patient-centricity and diversity of medical affairs activities and finds product launch activities particularly exciting. She found participation in the IFAPP course and the opportunity to meet virtually with other medical affairs professionals to be both valuable and enjoyable.

To read the essay in its entirety, please click [here](#).

POLIO ERADICATION: FALLING AT THE FINAL HURDLE?

The eradication of infectious diseases is one of the key objectives of WHO. Unfortunately, despite several decades of intense efforts, today we can claim we eradicated only smallpox.

The next disease candidate to global eradication is polio: the past 3 years have seen remarkable developments in this effort. In 2019, global eradication of type 3 poliovirus was declared. In 2020, Africa was classified as free from endemic polio. Wild poliovirus was confined to pockets of Afghanistan and Pakistan. But optimism is receding. Polio has returned to many parts of the world, and the upcoming replenishment to fund the eradication initiative comes amid geopolitical crises and global economic difficulties. The final stages of eradication have long been stuttering. Will 2022 be the year it finally slips away?



The low vaccination rate is responsible for a recent outbreak of polio in the New York area, and Poliovirus has now been detected in sewage samples from four counties in the New York metro area as well as in the city itself.⁵

Continue reading [here](#).

THE CDC ON ANTIMICROBIAL RESISTANCE



Antimicrobial resistance is an urgent global public health threat, killing at least 1.27 million people worldwide and associated with nearly 5 million deaths in 2019. It can affect people at any stage of life and may also have significant impacts on the healthcare, veterinary, and agriculture industries. These factors make it one of the world's most urgent public health problems.

In the U.S., more than 2.8 million antimicrobial-resistant infections occur each year. More than 35,000 people die as a result, according to CDC's 2019 Antibiotic Resistance (AR) Threats Report. When *Clostridioides difficile*—a bacterium that is not typically resistant but can cause deadly diarrhea and is associated with antimicrobial use—is added to these, the U.S. toll of all the threats exceeds 3 million infections and 48,000 deaths.

Keep reading [here](#).

THE SPUTNIK V VACCINE, THROMBOCYTOPENIA AND THROMBOSIS

Since its arrival on the market, the Sputnik vaccine was met with some suspicion. The Phase III study published in the Lancet had several mistakes which were then highlighted in letters to the editors. However, the publication was never retracted, and the Sputnik vaccine was widely distributed in Latin America, Asia, and Africa. One of the most severe side effects of the COVID 19 vaccines is the onset of very rare cases of thrombosis with thrombocytopenia syndrome, later named vaccine-induced immune thrombocytopenia and thrombosis (VITT). Estimations of the incidence of VITT range from 3.2 to 16.1 cases per million doses for the Pfizer and Astra Zeneca vaccines. The results of repeated searches of the literature indicated that no cases were reported after



the administration of the Sputnik V vaccine as of August 12, 2022. This is not in agreement with the reports of aggregated data published by the Argentinian Ministry of Health.⁶

Continue reading [here](#).

RWE AND ORAL ANTIVIRALS FOR COVID-19



Medical Affairs professionals are familiar with the importance of corroborating clinical evidence regarding new drugs from Phase II and III trials with results obtained from real-world evidence (RWE) studies. The included publication references RWE data related to oral antivirals in the treatment of COVID-19.

“In these populations, both antivirals were associated with a significant decrease in the relative risk of hospitalization or death: by 30% for molnupiravir and by 89% for nirmatrelvir plus ritonavir. Upon widespread use of these antivirals in 2022, further real-world data were needed to refine these results and to test their effectiveness under various conditions.”⁷

Keep reading [here](#).

EUROPEAN MEDICINES AGENCY QUALIFIES AI-POWERED METHOD FOR RUNNING SMALLER, FASTER CLINICAL TRIALS

The EMA released its final favorable qualification opinion providing a regulatory framework for the application of the TwinRCT™ solution in Phase 2 and 3 clinical trials. The three-step PROCOVA™ procedure is the foundation for TwinRCTs and describes how to use patient-specific prognostic scores derived from digital twins to reduce clinical trial sizes while controlling Type-1 error rates. This qualification opinion represents the first time a regulatory body has formally supported a machine learning-based method for reducing sample size in pivotal trials.

In their final opinion, the EMA stated that the Committee for Medicinal Products for Human Use



(CHMP) “qualifies PROCOVA” and that “the proposed procedures could enable increases in power and/or decreases in sample size in phase 2 and 3 clinical trials with continuous outcomes.”

Continue reading [here](#).

NEW CO-CHAIRS ELECTED FOR EMA WORKING PARTIES



EMA’s Patients’ and Consumers’ Working Party (PCWP) has elected Marilena Vrana of the European Heart Network (EHN) as new co-chair. The Healthcare Professionals’ Working Party (HCPWP) has elected Rosa Giuliani of the European Society for Medical Oncology (ESMO) as new co-chair. Together with Juan Garcia Burgos, Head of Public Engagement at EMA, they will co-chair the meetings of their respective working parties for the next three years. The vote took place during the September 2022 meeting of both working parties.

Marilena Vrana has extensive experience in membership associations and serves currently as Manager of Patients and Research at EHN. Rosa Giuliani is a medical oncologist. She is currently a Board member of ESMO. Since 2020, she is Director of Public Policy and Chair of the ESMO Global Policy Committee.

Read more about the new co-chairs [here](#).



Did you know that 90% of our past students agree that the program has had a significant impact in their work and enriched their life?

Join fellow professionals from around the world and advance your career with the 2023 IFAPP Academy-King's College London Certification Program of Medical Affairs in Medicines Development.

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

[Apply Today](#)

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.

REFERENCES

1. Weaver R, Peters K, Koch J, Wilson I. 'Part of the team': Professional identity and social exclusivity in medical students. *Med Educ.* 2011;45(12):1220-1229
2. Cruess RL, Cruess SR, Boudreau JD, Snell L, Steinert Y. Reframing Medical Education to Support Professional Identity Formation. *Academic Med.* 2014; 89:1446-1451
3. Cooper C. Research versus Standard of Care: Considerations for the Design & Implementation of your Study. ITHS: Clinical Research Education Series (CRES), June 2012. [Accessed 30th November 2021 via <https://www.iths.org/wp-content/uploads/Research-vs-SOC-ITHS-June-1-2012.pdf>]
4. Jarvis-Selinger S, Pratt DD, Regehr G. Competency is not enough: Integrating identity formation into the medical education discourse. *Academic Med.* 2012;87(9):1185-1190
5. Lancet, T. (2022, October 1). Polio eradication: falling at the final hurdle? *The Lancet.* [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(22\)01875-X/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)01875-X/fulltext)
6. Herrera-Comoglio, R., & Lane, S. (2022). Vaccine-Induced Immune Thrombocytopenia and Thrombosis after the Sputnik V Vaccine. *New England Journal of Medicine*, 387(15), 1431–1432. <https://doi.org/10.1056/nejmc2210813>
7. Burdet, C. (2022, October 8). Real-world effectiveness of oral antivirals for COVID-19. *The Lancet.* [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(22\)01929-8/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)01929-8/fulltext)Manfrini, O. (2022, September 10). Behavioural risk factors and cardiovascular disease: are women at higher risk? *The Lancet.* Retrieved October 21, 2022, from [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(22\)01736-6/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)01736-6/fulltext)

Thanks for reading!

The IFAPP 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, Jean Ferreira, Gustavo Kesselring, Honorio Silva, Peter Stonier

Operations Office: Haley Loving, Amanda Schmitt, Gustavo Silva, Kiet Vo

CONTACT US:



420 Lexington Ave. Ste. 300

New York, NY 10170

(332) 333-2438