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A CELEBRATION OF GLOBAL FELLOWS IN MEDICINES DEVELOPMENT

As reported by Peter Stonier and Pravin Chopra

The Great Hall of King's College London set the stage Monday 22 May 2023, for an illustrious Award ceremony.

The event was to welcome and felicitate 72 prime contributors to the research and availability of medicines for the treatment and benefit of patient communities around the world – an acknowledgment richly deserved from a dedicated career path and outstanding contributions to medicines development through sustained endeavor. The prestigious award of Global Fellow in Medicines Development (GFMD) comes after rigorous assessment of the nominee's academic and vocational record, experience and achievement in this multidisciplinary scientific and medical enterprise, with societal contribution and recognition. Continue reading [here](#).

PROFESSIONAL IDENTITY AND MEDICINES DEVELOPMENT: INSIGHTS FROM ACADEMY ALUMNI

Continuing our series on [Professional Identity](#) and Medicines Development, we are pleased to publish another insightful essay from a graduate of our 2022 cohort, Robin Henocque.

“

The aspects of Professional Identity and sense of purpose are very important to define because they determine our purpose as Medicines Development professionals. From my point of view, the role of Medicines Development was created for a very clear purpose: to create a medical and scientific link between our pharmaceutical industry, the scientific community and society. Indeed, for the pharmaceutical industry to be recognized as a public health actor, it was necessary to create a department of experts and scientific referents. Medicines Development professionals contribute to the scientific foundations of the pharmaceutical industry.

Our Professional Identity is defined by our role as a scientific expert within the pharmaceutical industry. We are responsible for the quality of the data generated and the communication of scientific messages to the medical community and the public. Clearly, we are the bridge between clinical research and drug commercialization. We are involved in setting up clinical studies and research projects in collaboration with clinical centers and academic structures to develop new treatments and generate new scientific data. These studies are based on the identification of unmet medical needs through collaboration with the health care ecosystem, the scientific community, and patients.

”



Robin Henocque is currently Global Medical Director at Pfizer and graduated from the Academy in the year 2022. Robin has a PharmD from the University of Pharmacy of Grenoble (France) and completed a university degree in methods and practice in medico-economic evaluation, as well as a master's degree in Pharmaceutical Marketing and Health Technologies.

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

THE DOBBS DECISION: EXACERBATING U.S. HEALTH INEQUITY

The U.S. Supreme Court's decision on June 24, 2022, to overturn Roe v. Wade and eliminate federal protection for abortion has dealt a significant blow to reproductive health care in the United States and exacerbated health inequity in the country. States now have the authority to ban abortion, leading to increased inequalities in the healthcare system and society. The impact of these restrictions will be particularly severe for low-income women and marginalized racial and ethnic groups. This decision in the Dobbs case is expected to perpetuate and worsen existing health disparities, which have long been prevalent in the country.



It is a setback for reproductive rights and may result in limited access to safe and legal abortion, forcing vulnerable communities to seek risky alternatives and exacerbating the unequal distribution of healthcare resources. Keep reading [here](#).¹

INSIGHTS FROM THE IQVIA INSTITUTE GLOBAL TRENDS IN R&D REPORT



The IQVIA Institute recently released a report that highlights several intriguing findings regarding the global launch of novel active substances (NASs) in 2022. While there was a slight decline compared to the previous two years, with 64 NASs launched, it marks a return to pre-COVID-19 levels. The report also sheds light on the therapeutic areas that have seen a significant increase in new launches over the past five years, namely oncology, neurology, and immunology, accounting for almost half of all launches. Additionally, the study emphasizes the importance of infectious disease treatments, including those for COVID-19, as well as other viruses, bacteria, fungi, and parasites. These treatments have constituted a notable portion of NAS launches in the past decade, with certain fluctuations observed from year to year. The findings from this report provide valuable insights into the evolving landscape of pharmaceutical innovations and the impact of recent global health challenges on drug development and launches. Access the report [here](#).²

PRAGMATIC TRIALS, POLICY DECISIONS, AND PLANNING

The Lancet Infectious Diseases presents a significant vaccine trial conducted amidst challenging pandemic circumstances, addressing pressing national, regional, and global policy questions regarding pragmatic trials, policy decisions, and planning. Researchers focused on adults previously vaccinated with two doses of inactivated COVID-19 vaccine, randomly assigning them to receive boosters in different groups, including homologous and heterologous options. The study examined neutralizing and binding antibody titres in relation to the ancestral virus and the delta variant, primarily comparing full-dose and half-dose recipients. Results indicated similar responses across all groups, with minor adverse events observed to be lower in the half-dose recipients.



Crucial remaining questions revolve around the duration of immune responses, especially in regard to cell-mediated immunity, and the need for follow-up studies in different populations and against emerging variants. It highlights the importance of pragmatic, cross-platform investigations for effective vaccination strategies. Read more [here](#).³

COVID-19 OUTCOMES ACROSS STATES



In the USA, there has been substantial variation in COVID-19 outcomes across states. In exploring the reasons for this variation, the authors used correlations and multiple regression to assess the independent contributions of socioeconomic status, income inequality, race, behavioral responses, policy mandates, and support for political candidates to SARS-CoV-2 infection rates, COVID-19 deaths, and educational and employment outcomes. Their analysis showed that wide variations in pre-pandemic population characteristics between states were strongly associated with COVID-19 outcomes. COVID-19 mortality was highly correlated with poverty rate (with a one SD increase from the US mean associated with a 23.3% [95% uncertainty interval 14.8–32.5] increase in the cumulative death rate) and degree of income inequality (with a one SD increase associated with an 11.6%₄ [2.7–21.3] increase in the cumulative death rate).

Read more [here](#).

EMA NEWS: ESTABLISHING EFFICACY BASED ON SINGLE-ARM TRIALS

The European Medicines Agency has published for public consultation a [draft reflection paper on establishing efficacy based on single-arm trials submitted as pivotal evidence in a marketing authorisation](#).

Randomised controlled trials (RCTs) are the standard for providing confirmatory evidence on the efficacy of a new treatment. However, in a relevant proportion of marketing authorisation applications the pivotal clinical data stems from single-arm trials (SATs). This is observed across different therapeutic areas, including for rare diseases. The purpose of this reflection paper is to outline the current thinking about SATs that are submitted as pivotal evidence for establishing efficacy in marketing authorisation applications.



Comments should be provided using a specific template and sent to RP-SATs@ema.europa.eu by 30 September 2023.⁵

Read more [here](#).



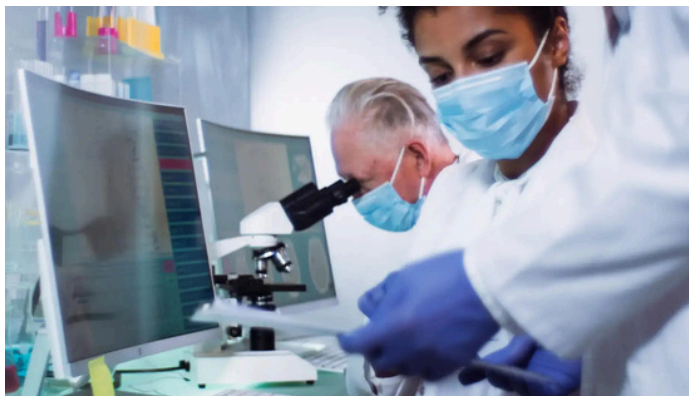
RACIAL AFFINITY GROUP CAUCUSING IN MEDICAL EDUCATION

A recent article from the New England Journal of Medicine addresses racism in medicine and highlights the need for new approaches in medical education to address racism as a root cause of health disparities. The focus is on racial affinity group caucuses (RAGCs), which are facilitated sessions where participants gather based on their self-identified racial or ethnic identity.

These sessions aim to integrate anti-racism curricula into clinical practice by fostering critical introspection, building community, and encouraging the integration of theory, self-reflection, and action, ultimately equipping physicians to tackle health inequities. "Addressing racism in medicine requires approaches at the systemic, interpersonal, and individual levels. RAGCs are designed to support learning, growth, and reflection in a manner that centres BIPOC learners while providing differentiation for all learners. We suggest using longitudinal RAGCs throughout medical school and in residency programs as an opportunity for learners to contextualize antiracism curricula, bring greater depth and meaning to such curricula's lessons, build supportive communities, and expand knowledge and skill in antiracist doctoring. RAGCs are a promising approach to equipping physicians to help eliminate health inequities."⁶

Keep reading [here](#).

EMA RESOURCE: WELCOME TO CLINICAL TRIALS HIGHLIGHTS



Clinical Trials Highlights is a quarterly newsletter produced and released by the EMA. It contains news on ongoing trials in Europe, as well as useful suggestions for the correct implementation of the New European Regulation on Clinical Trials.

Access the most recent Clinical Trials Highlights newsletter [here](#).

ROSALIND FRANKLIN'S CONTRIBUTIONS TO THE DISCOVERY OF DNA'S STRUCTURE

A recent article in Nature discusses the popular narrative surrounding the discovery of the double helix structure of DNA and the role of scientist Rosalind Franklin. According to the lore, James Watson had a breakthrough after viewing an X-ray image of DNA, known as Photograph 51, taken by Franklin without her permission or knowledge. Franklin, who passed away at a young age, is portrayed as a brilliant scientist who failed to recognize the significance of her own data, while Watson quickly understood it.

This version of events has become widely known, permeating popular culture. It inspired a play called "Photograph 51" starring Nicole Kidman in 2015, and even appeared on a British 50 pence coin commemorating Franklin's birth centenary in 2020. The story has also been the subject of jokes on Twitter and a rap battle performed by seventh-grade students in Oakland, California.⁷

Continue reading [here](#).



Scientist Rosalind Franklin. Credit: Photo Researchers/Science History Images/Alamy/Nature

REFERENCES

1. Harvey, S. M., Larson, A. E., & Warren, J. T. (2023). The Dobbs Decision — Exacerbating U.S. Health Inequity. *The New England Journal of Medicine*, 388(16), 1444–1447. <https://doi.org/10.1056/nejmp2216698>
2. 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>
3. Bar-Zeev, N., & Ndeketa, L. (2023). Pragmatic trials to inform policy decisions and planning. *The Lancet Infectious Diseases*, 23(5). [https://doi.org/10.1016/s1473-3099\(22\)00830-1](https://doi.org/10.1016/s1473-3099(22)00830-1)
4. Lurie, N., & Sharfstein, J. M. (2023). State-to-state differences in US COVID-19 outcomes: searching for explanations. *The Lancet*, 401(10385), 1314–1315. [https://doi.org/10.1016/s0140-6736\(23\)00726-2](https://doi.org/10.1016/s0140-6736(23)00726-2)
5. Ema. (2023, April 17). Reflection paper on establishing efficacy based on single-arm trials submitted as pivotal evidence in a marketing authorisation. https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-establishing-efficacy-based-single-arm-trials-submitted-pivotal-evidence-marketing_en.pdf
6. Lewis, L., Fabersunne, C. C., Iacopetti, C. L., Negussie-Retta, G., McBride, D., Irving, P., & Marbin, J. (2023). Racial Affinity Group Caucusing in Medical Education — A Key Supplement to Antiracism Curricula. *The New England Journal of Medicine*, 388(17), 1542–1545. <https://doi.org/10.1056/nejmp2212866>
7. Cobb, M., & Comfort, N. (2023). What Rosalind Franklin truly contributed to the discovery of DNA's structure. *Nature*, 616(7958), 657–660. <https://doi.org/10.1038/d41586-023-01313-5>

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