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PROFESIONAL IDENTITY AND MEDICINES DEVELOPMENT

Continuing our series on Professional Identity and Medicines Development, we are thrilled to showcase an exceptional essay from Kripa Madnani, a member of our 2023 cohort. Kripa's essay delves deeply into the significance of Professional Identity within the field of medicines development, emphasizing its vital role in shaping ethical practices, promoting lifelong learning, and ultimately enhancing patient outcomes.

The Academy is grateful to Kripa for her thoughtful and impactful contribution to our ongoing discussions on this important topic. Continue to page 2 to read her essay.

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PROFESSIONAL IDENTITY & MEDICINES DEVELOPMENT

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Academy Alumni Perspectives: Kripa Madnani, PhD

"In the medicines development profession, knowledge, skills, and behaviors need to be cultivated across domains, with an awareness of clinical development, regulatory guidelines, medical ethics, health economics, access to medicine, and ongoing research and development. Generally considered the "bridge" between research and development and commercial teams, medicines development professionals need to be adept communicators, have the ability to work well in teams and manage multiple stakeholders, while ensuring that all ethical standards are followed and that the patient is at the center of the business. Key values for medicines development professionals include integrity and commitment to excellence.

In terms of demonstrable professional behaviors, this includes being a good negotiator, great listener, with the ability to think about issues strategically and combine perspectives and insights in a meaningful way. While standard undergraduate and graduate-level courses may address the technical aspects of work as a medicines development professional, several other determinants of success such as teamwork, communication, strategic thinking, stakeholder management and others may be inculcated via the process of self-awareness and professional identity formation."

Read her complete essay here.

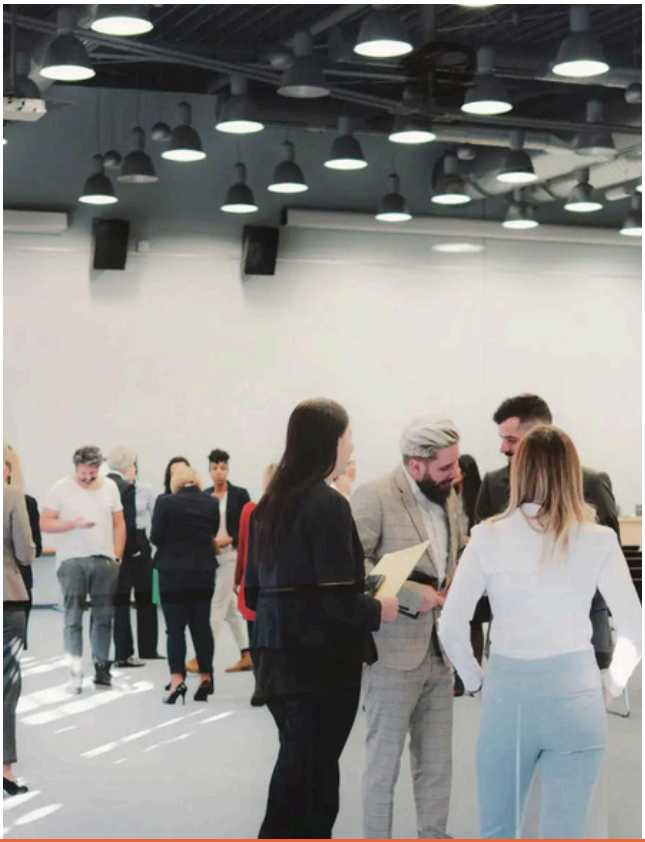
Over the last 10 years, Kripa Madnani has been involved in various aspects of medical and biological research, including laboratory research in an academic environment and medical communications in consultant (agency service providers) and pharmaceutical company (client) environments. During her PhD, Kripa worked on malaria infection and cell biology in an international academic setting. Currently, as part of the medical and scientific content creation and communications team at Pfizer (and previously at other companies), Kripa collaborates with global stakeholders in various therapeutic areas, including infectious diseases, oncology, neurobiology, and immunology, among others. She has had the opportunity to work with medical affairs professionals from different specialties and has experienced changes in dynamics, regulatory frameworks, and industry expectations. Her past experience includes contributing to research papers, conducting gap analyses of data for post-launch molecules, developing global value dossiers for formulary submission, and creating patient-facing content. Kripa is currently leading a team of eight medical communications professionals.

FDA SUPPORTS MORE TREATMENTS FOR RARE DISEASES WITH THE "START" PILOT PROGRAM

The article highlights the significant advancements in science leading to potential treatments for rare diseases, such as gene therapies and drugs affecting gene expression, which were previously unimaginable. However, many rare diseases still lack treatment options, necessitating further efforts to alleviate patient and family suffering.

To address this, the FDA has launched the Support for Clinical Trials Advancing Rare Disease Therapeutics (START) Pilot Program, spearheaded by the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER). The START Pilot Program aims to accelerate the development of novel drugs and biologics for rare diseases.[2] Continue reading here.

THE EMA AND THE AGING POPULATION

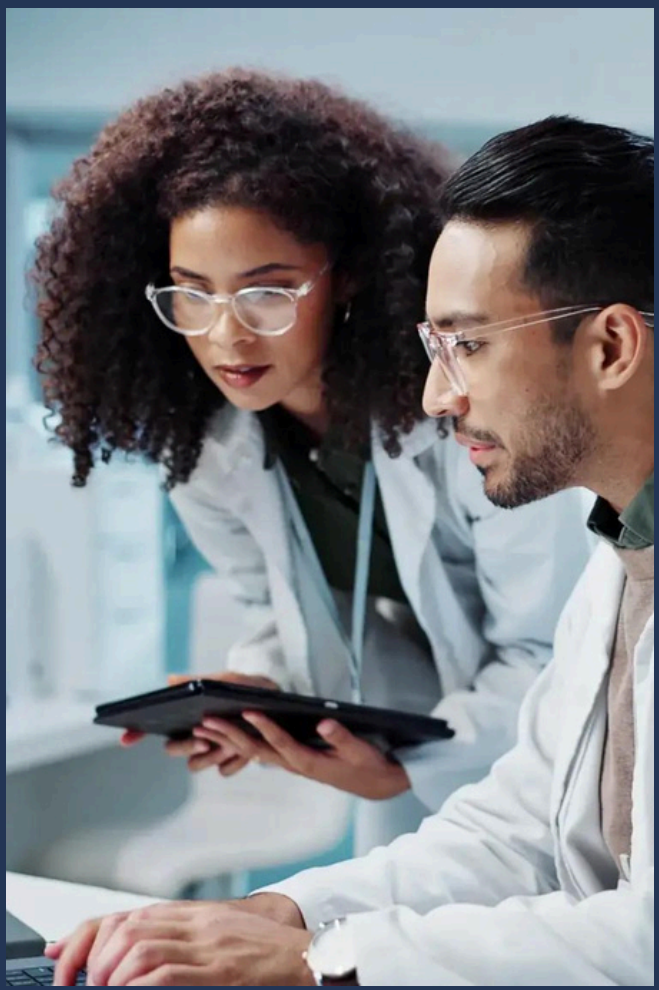


The article "Medicines for an Aging Population: The EMA Perspective and Policies," recently published in the Journal of the American Geriatrics Society, discusses the European Medicines Agency's (EMA) Geriatric Medicines Strategy, which was adopted over a decade ago. The strategy focuses on improving the evidence base for marketing new medicines for older adults and ensuring clear communication of findings to patients and healthcare providers.

The article emphasizes the importance of addressing the specific needs of older patients and integrating these considerations into the entire lifecycle of medicines.[3] Continue reading here.

OUR HEALTH UNDER ATTACK

The recent cyberattack on Change Healthcare is described as the most significant and consequential incident of its kind against the U.S. healthcare system. Rick Pollack, President and CEO of the American Hospital Association (AHA), underscores its severity. The attack, which occurred in February, disrupted the largest U.S. billing and payment system, affecting millions of patients' prescriptions and services and delaying access to medications and care. Even two months post-attack, an AHA survey revealed that many medical practices faced potential closure due to lost revenue from unpaid claims, threatening patient access to medical services.[4] Keep reading here.



REAL-WORLD DATA AND REAL-WORLD EVIDENCE IN REGULATORY DECISION-MAKING

CIOMS is pleased to announce that the consensus report of the CIOMS Working Group XIII on "Real-world Data and Real-world Evidence in Regulatory Decision Making" was published. The report aims to:

- Describe the potential use of RWE for decision-making.
- Discuss RWD and its sources.
- Highlight key scientific considerations in generating RWE.
- Address ethical and governance issues in using RWD.[5]

Access the full report here.

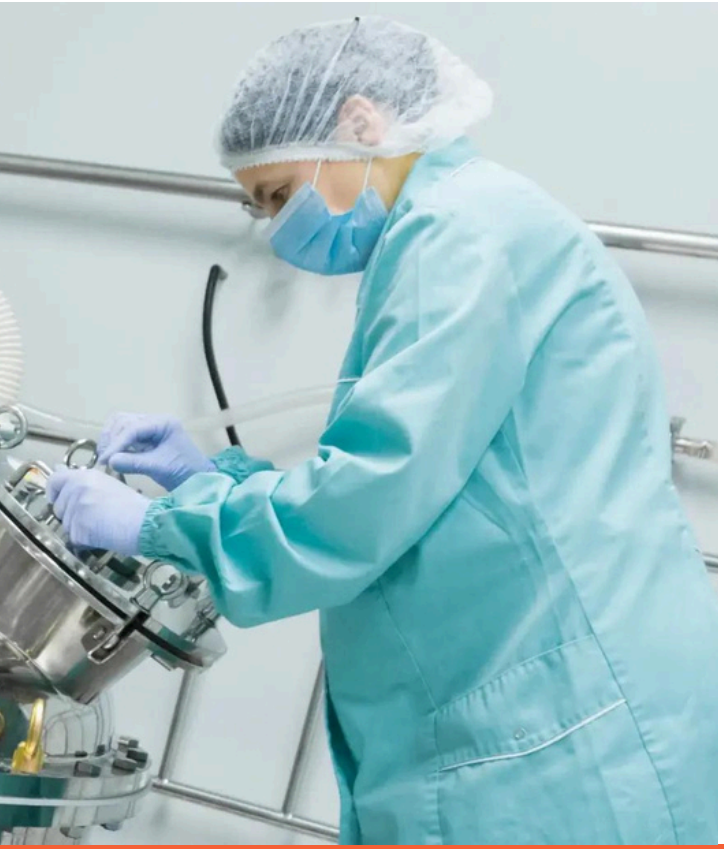
MORE ATTENTION TO ANTIMICROBIAL RESISTANCE

In 2016, antimicrobial resistance (AMR) gained significant political attention, culminating in a UN high-level meeting where member states committed to a coordinated effort to tackle AMR across human health, animal health, agriculture, and environmental health. However, eight years later, progress has been limited. Although 178 countries have developed national action plans, fewer than 20% are funded or implemented. To accelerate efforts, the UN is hosting another high-level meeting in September, aiming to spur global, regional, and national actions against AMR. This meeting seeks to make meaningful progress on this critical health threat of the 21st century.

A new Series on AMR offers key evidence on interventions and investments necessary for sustainable access to effective antibiotics and outlines strategies to accelerate progress. It also proposes achievable global targets for humans and animals by 2030.

The upcoming UN meeting and the insights from the Lancet Series aim to drive significant advancements in combating AMR by addressing these fundamental issues and promoting equitable global health strategies.[6] Keep reading here.

IMPORTANT NEWS FROM THE CDRH



The CDRH is pleased to announce the continued expansion of the Total Product Life Cycle (TPLC) Advisory Program (TAP). This expansion will include devices reviewed in the Office of Radiological Health (OHT8) and the Division of Ophthalmic Devices (DHT1A) in fall 2024, followed by the Office of Orthopaedic Devices (OHT6) in 2025.

CDRH initiated the TAP Pilot in 2023 as part of the Medical Device User Fee Amendments (MDUFA) V reauthorization. The program aims to accelerate the development of high-quality, safe, effective, and innovative medical devices crucial to public health.[7]

Continue reading here.

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Thanks for reading!

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