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PROFESSIONAL IDENTITY AND MEDICINES DEVELOPMENT

Ankita Mukherjee, a graduate of the GMDP Academy, offers a unique perspective on the journey of developing a professional identity (PI). In her essay, Ankita explores the deeply personal and evolving nature of PI, highlighting how an individual's motivations, values, and experiences shape their professional self. Drawing from her own academic journey, she emphasizes that PI formation is an ongoing process influenced by personal growth, educational environments, and societal interactions.

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ANKITA MUKHERJEE, MSC, PGDHHM, CMD

Professional Identity plays a crucial role in the overall healthcare system & Medical Affairs including Medicines Development. In the clinical setting, it has been observed that strong professional identity is effective for good patient safety, better practice & increased satisfaction associated with it, great patient outcomes, reduced stress, and improved retention and recruitment of practitioners. On the other hand, the lack of / weakened professional identity may lead to increased stress, decreased self-confidence & decision-making ability, moral distress, etc.[1]

PI formation is not an easy goal to achieve. It requires intentional design, guided reflection, strong role modeling, new forms of student learning assessments, new forms of program evaluation, and faculty and preceptor development.[2]

With regards to the significance of Medical Affairs, McKinsey Paper – A vision for Medical Affairs in 2025 can be quoted – "Medical Affairs is the third strategic pillar of the organization alongside R&D and Commercial".[3]

The Jandhyala paper describes that Medical Affairs "is the medical specialty that protects patients' interests by regulating pharmaceutical company activities and leads medicine adoption through the design, implementation and communication of real-world evidence targeted to the needs of regulators, payors, prescribers and patients".[4]

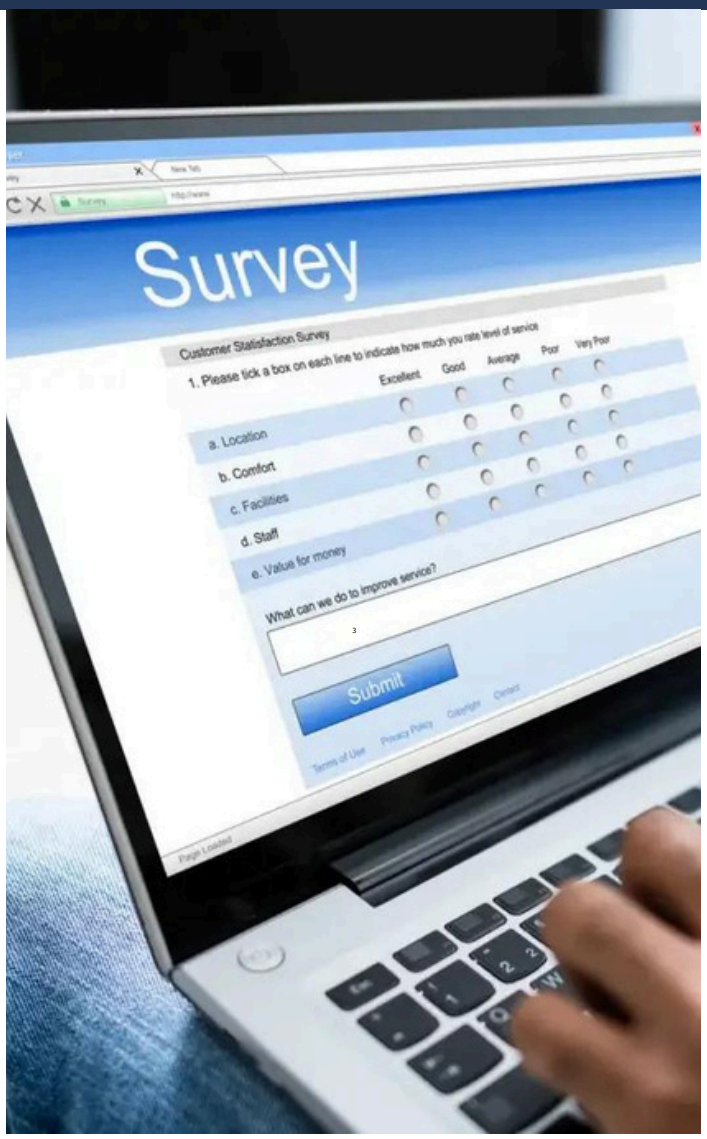
The above short descriptions reiterate the fact that Medical Affairs involves cross-collaboration of multiple interconnected functions, including Drug Development. Additionally, basic concepts of PI & clarity of thoughts about Sense of Purpose are the cornerstones of the entire process to pave the way forward for optimum utilization of resources, superlative patient outcomes & an overall smooth operation.

- Ankita Mukherjee, MSC, PGDHHM, CMD

Ankita is a Nutritionist by training, and she has more than a decade of Medical Affairs experience in the diverse domains of Nutrition, Nutraceuticals & Pharmaceuticals. She is currently working with Pfizer as a Medical Manager. Ankita loves traveling and firmly believes in the words: *Never give up, miracles happen every day.*

To read Ankita's essay in its entirety, click here.

PROPOSED CHANGES TO THE CTIS ROLES MATRIX: SUBMIT YOUR FEEDBACK BY SEPTEMBER 15, 2024



The EMA's Clinical Trials Information System (CTIS) Simplification Force is proposing changes to the CTIS roles matrix. Sponsors are invited to review these proposed simplifications, which are detailed in an EU Survey, and submit feedback by September 15, 2024.

Sponsors are encouraged to provide a consolidated response for their organization (one response per sponsor organization).[5]

Access more details here.

VACCINES' PROTECTION FROM INFECTIOUS DISEASES

Vaccines are crucial for ensuring children's health from birth and as they grow. Due to the success of immunization programs, many parents today may not realize that vaccine-preventable diseases could reemerge if vaccination rates decline. Diseases that were once common in the U.S., such as measles, polio, diphtheria, rubella, and chickenpox, are now preventable through FDA-approved vaccines. The FDA ensures that all vaccines meet rigorous safety, effectiveness, and quality standards.[6]

Continue reading here.

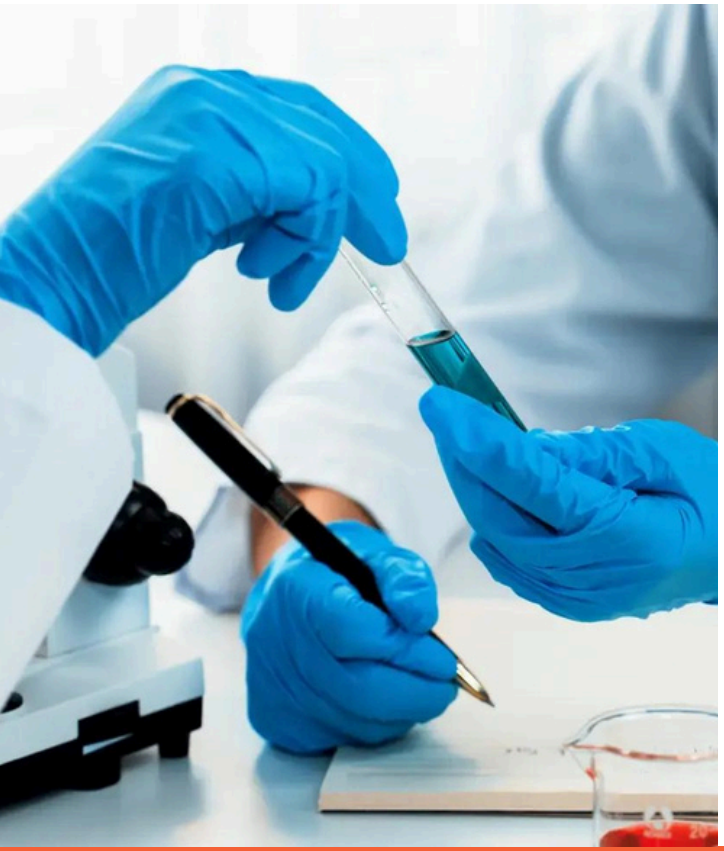
HOW EGFR-TARGETED THERAPY REVOLUTIONIZED LUNG CANCER SURVIVAL

Before 2000, lung cancer had a very high mortality rate, with limited treatment options and a 1-year survival rate of only 33% for advanced cases. However, through EGFR, lung cancer survival rates have dramatically improved. The approval of EGFR-targeted therapy in 2003 and the discovery of EGFR gene mutations in 2004 spurred the search for other mutations. Over the past 20 years, targeted therapies have dramatically increased survival rates, with some patients now living over 50 months. Biomarker testing is now standard in lung cancer care, and new studies like the CROWN and LAURA trials, presented at the 2024 ASCO Annual Meeting, promise further advancements for patients with challenging metastatic disease.

The discovery of other actionable mutations, including ALK and ROS1, led to the development of additional targeted therapies.

The discovery of other actionable mutations, including ALK and ROS1, led to the development of additional targeted therapies, transforming lung cancer treatment into a precision medicine approach.[7] Read more here.

EMA DRIVES INNOVATION IN EU CLINICAL TRIALS AND LONG COVID RESEARCH



Below are summaries of the two articles co-authored by the European Medicines Agency (EMA):

1. Accelerating Clinical Trials in the EU (ACT EU): The ACT-EU initiative is making significant progress in transforming the EU's clinical trials landscape. Key achievements include enhancing the Clinical Trials Information System, advancing Clinical Trial Regulation, and publishing important guidance.[8]
2. Generating Clinical Evidence for Long COVID: The EMA organized a workshop on November 17, 2023, focusing on generating clinical evidence for the treatment and prevention of long COVID. The workshop emphasized the need for well-designed clinical trials to support regulatory recommendations.[9]

Read more here.

FDA RECOGNIZES AI/ML'S ROLE IN ADVANCING DRUG DEVELOPMENT AND CLINICAL TRIALS

The FDA acknowledges the growing role of artificial intelligence and machine learning (AI/ML) in drug development, recognizing their potential to speed up the process. AI/ML can be particularly useful in clinical trial patient selection, where it can predict outcomes based on various baseline characteristics, such as demographic information, clinical data, and medical imaging. By identifying patients who are more likely to respond well or have poorer prognoses, these models can enhance the demonstration of a drug's effectiveness.

AI/ML technologies are transforming drug development by analyzing large datasets more rapidly and accurately than traditional methods. This capability allows researchers to identify patterns and correlations that may not be apparent otherwise.

By improving patient selection, AI/ML models can help ensure that clinical trials are more efficient, reducing both time and costs associated with drug development.[10]

Read more here.

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Thanks for reading!

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