GMDP academy
ISSUE 57 • OCT. 18, 2024

PROFESSIONAL IDENTITY AND MEDICINES DEVELOPMENT

Continuing our series on the importance of Professional Identity in Medicines Development, here is the essay prepared by Manoj Patil, as part of the 2023 end of course assessment. In his essay, he delves into how PI is shaped by knowledge, attitudes, values, and skills, emphasizing its continuous evolution throughout a professional's career. Manoj discusses the role of Medical Affairs professionals in sharing real-world evidence (RWE) to support medicines development and how their professional identity is defined by this contribution.[1]

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Academy Alumni Perspectives: Manoj Patil

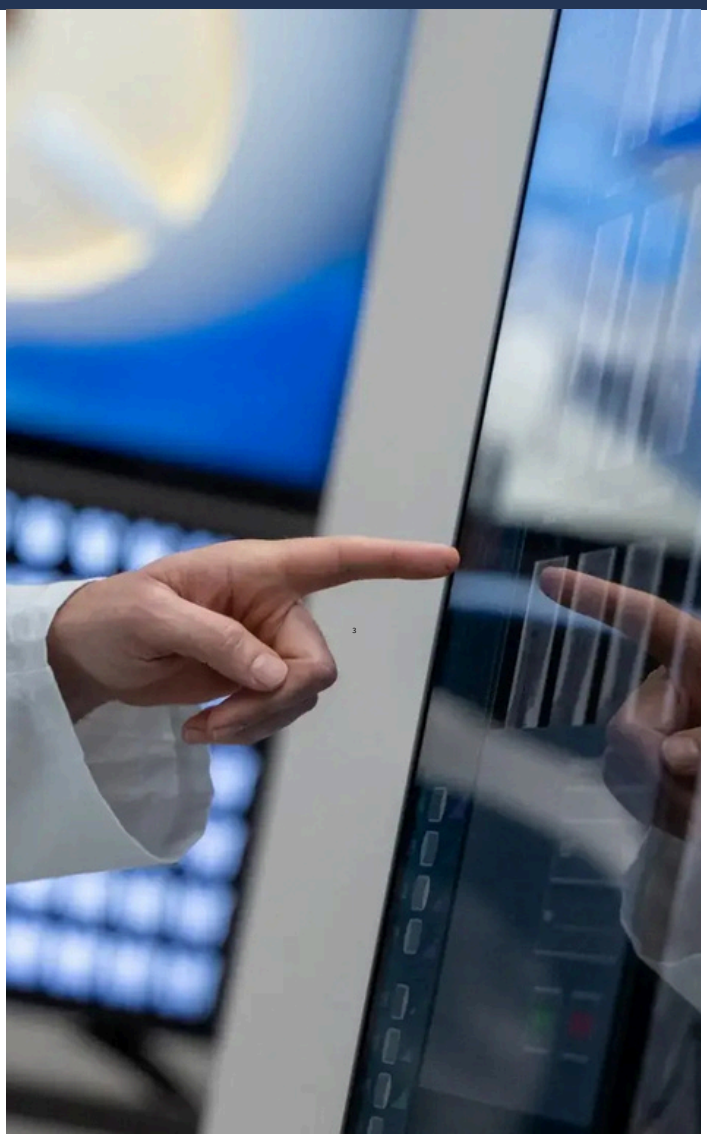
"Professional Identity (PI) refers to how an individual perceives themselves, including their knowledge, understanding, and attitude toward the role they perform in a profession. In the field of medicines development, PI is best demonstrated through a thorough understanding of the medicines development process and its scientific foundation. PI is a complex structure involving multiple facets throughout a professional's career, including but not limited to their motivation, attitudes, values, knowledge, beliefs, and skills. Its development must be an ongoing process, continually evolving over time.

In Medical Affairs, professionals are tasked with sharing medical insights and real-world evidence (RWE) derived from real-world data (RWD). This significantly contributes to the overall medicines development process, promoting cost savings and reducing efforts. As such, their professional identity is closely tied to this approach.

The cultivation of individual professional identities is crucial for all healthcare professionals to ensure optimal patient care. A clear sense of PI is necessary for promoting the perceived value of the profession and for healthcare professionals to advocate for their unique contributions to patient care[1]. Read Manoj's complete essay **here**.

Manoj Patil joined Pfizer in 2021 as the Medical Manager for GMAIST. In this role, he supports literature database research, evaluates Health Hazard Assessments (HHA), and contributes to the benefit-risk assessments of Pfizer products. His responsibilities also include assisting with major regulatory agency submissions and Clinical Overviews (CO).
Manoj holds a postgraduate degree in pharmacology and brings over 14 years of prior industrial experience in Medical Writing and Clinical Data Management (CDM). He has previously worked with Tata Consultancy Services (TCS) and Cognizant Technology Solutions. In his leisure time, Manoj enjoys reading books and newspapers and exploring new places with his family.

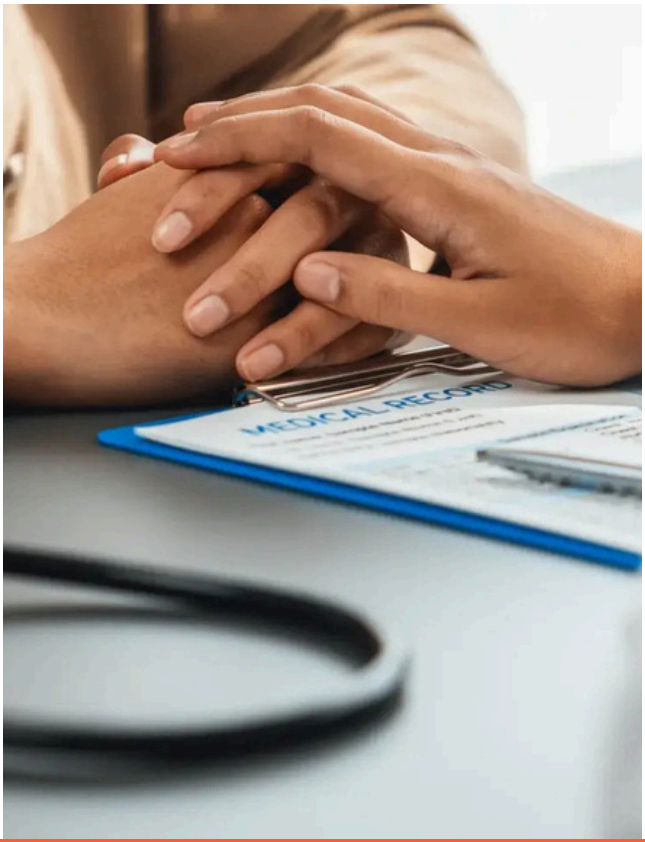
HOW REAL-WORLD EVIDENCE SUPPORTS EU REGULATORY DECISIONS: INSIGHTS FROM EMA'S PILOT PROJECT



The article "Real-World Evidence (RWE) to Support EU Regulatory Decision Making: Results from a Pilot Regulatory Use Cases," co-authored by the European Medicines Agency (EMA) and published in Clinical Pharmacology & Therapeutics, highlights the role of real-world data (RWD) in complementing clinical trial evidence and addressing gaps during a medicine's lifecycle. It reviews EMA's pilot project from September 2021 to February 2023, which aimed to generate RWE for EU regulatory evaluations.[2]

Continue reading here.

NEW FRONTIERS IN CANCER CARE

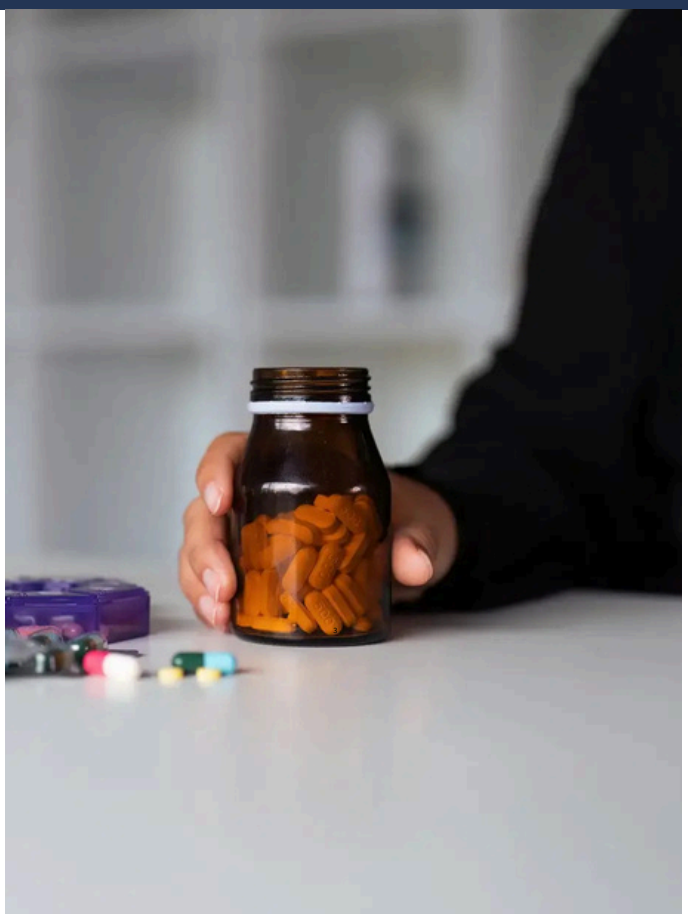


Whole-genome sequencing in cancer treatment (WGS) is increasingly recognized for its potential by providing detailed biological information about tumors. National initiatives in countries like England, Australia, and Sweden have started incorporating WGS for certain cancer patients. However, the impact on long-term patient outcomes of whole-genome sequencing in cancer treatment remains largely unstudied.

A study in England, published on July 2, 2024, evaluated WGS in routine care for children with cancer, finding that WGS provided additional clinical information for 29% of patients and led to treatment changes for 7%.[3] Continue reading here.

BOXED WARNINGS PERCEPTIONS BY CONSUMERS

As we know, the benefit/risk ratio of any drug can be defined only when it is on the market, and after several thousand patients have taken it: and therefore, it often happens that the information about its safety must be updated regularly. The Center for Drug Evaluation and Research (CDER) plays a key role in providing safety information about medicines, particularly through boxed warnings (BWs) on prescription drug labels. These warnings highlight serious risks to help healthcare providers (HCPs) and patients make informed decisions. A qualitative study was conducted by CDER and researchers to examine how HCPs interpret and communicate BW information when making treatment decisions. The study focused on two medicines with BWs: an oral antiviral for hepatitis C (HCV) and an estrogen vaginal insert for vulvovaginal atrophy (VVA). Interviews with 52 HCPs revealed how BWs influence their risk-benefit assessments and patient discussions.



Interviews with 52 HCPs revealed how BWs influence their risk-benefit assessments and patient discussions.[4]

Continue reading here.

INVITATION TO SUBMIT COMMENTS TO A NEW GUIDELINE

Guidelines on drug and vaccines development are very useful, as they indicate the most successful process to be implemented. The EMA has now released an addendum to its “Guideline on clinical development of vaccines” for public consultation. This addendum specifically addresses clinical trials involving immunocompromised individuals, an area not covered in detail in the original guideline.

Public comments on the addendum are invited until October 31, 2024 through an EU survey.[5]

Read more here.

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Thanks for reading!

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