GMDP academy
ISSUE 48 • MAY 28, 2024

ELEVATE YOUR EXPERTISE: INTRODUCING GMDP ACADEMY'S SHORT COURSES FOR MEDICINES DEVELOPMENT PROFESSIONALS

Are you a Medicines Development Professional looking to sharpen your skills or delve into a specialized area of pharmaceuticals? Look no further than GMDP Academy's newly launched short courses tailored specifically for busy healthcare practitioners like you. Our short courses provide a convenient and effective pathway for expanding your expertise and staying abreast of the latest advancements in the field. Explore the offerings below and get more details by clicking here.

TABLE OF CONTENTS

UNDERSTANDING THE SIGNIFICANCE OF HEALTH ECONOMICS AND OUTCOMES RESEARCH (HEOR) IN MEDICINES DEVELOPMENT

HEOR plays a crucial role in determining the value of new medicines and treatments, influencing both clinical decisions and healthcare policies. By integrating data from various sources, including clinical trials and patient reports, HEOR helps in understanding the economic impacts, quality of life outcomes, and overall effectiveness of healthcare interventions.

HEOR is integral to the development of new medicines as it provides a framework for understanding the balance between cost and benefit. This field of research assesses not only the therapeutic impact of a drug but also its economic viability, ensuring that the benefits justify the costs.

This is particularly important in a time when healthcare budgets are constrained and the need for effective, cost-efficient treatments is high.

The primary focus of HEOR is to support evidence-based decision-making. By analyzing various health outcomes and associated economic factors, HEOR specialists can provide recommendations that support the most beneficial and efficient use of resources in healthcare settings. Read more here.

ELEVATE YOUR CAREER WITH THE CLINICAL TRIALS I SHORT COURSE AT GMDP ACADEMY

In the dynamic field of clinical research, staying updated with the latest skills and knowledge is not just advantageous—it's essential. The GMDP Academy is proud to offer the Clinical Trials I Short Course, a program meticulously designed to deepen your understanding and enhance your expertise in clinical trial management. This course, titled "Essentials of Clinical Trial Management," is an excellent opportunity for professionals looking to make significant strides in their careers. The Clinical Trials I Short Course covers the fundamental aspects necessary to conduct successful clinical trials. Participants in the program will understand ethical principles, develop protocols, select optimal research sites, manage adverse events, and improve study quality through monitoring. Keep reading here!

THE EMA IS LOOKING FOR COMMENTS TO A DRAFT GUIDELINE ABOUT RWD AND RWE IN MEDICINES DEVELOPMENT FOR REGULATORY FILINGS.

The European Medicines Agency (EMA) has announced the opening of public consultation on the Draft Reflection paper regarding the use of real-world data in non-interventional studies to generate real-world evidence. This paper discusses methodological and data quality aspects of such studies for regulatory purposes.

Interested parties involved in planning, conducting, and analysing non-interventional studies using real-world data are invited to provide feedback on the draft reflection paper by August 31, 2024.

Additionally, a dedicated session will be held during the multi-stakeholder joint HMA-EMA workshop on RWE methods on June 14, 2024.[1] Read more here.

PRELIMINARY RESULTS FROM THE GLOBAL BURDEN OF DISEASES

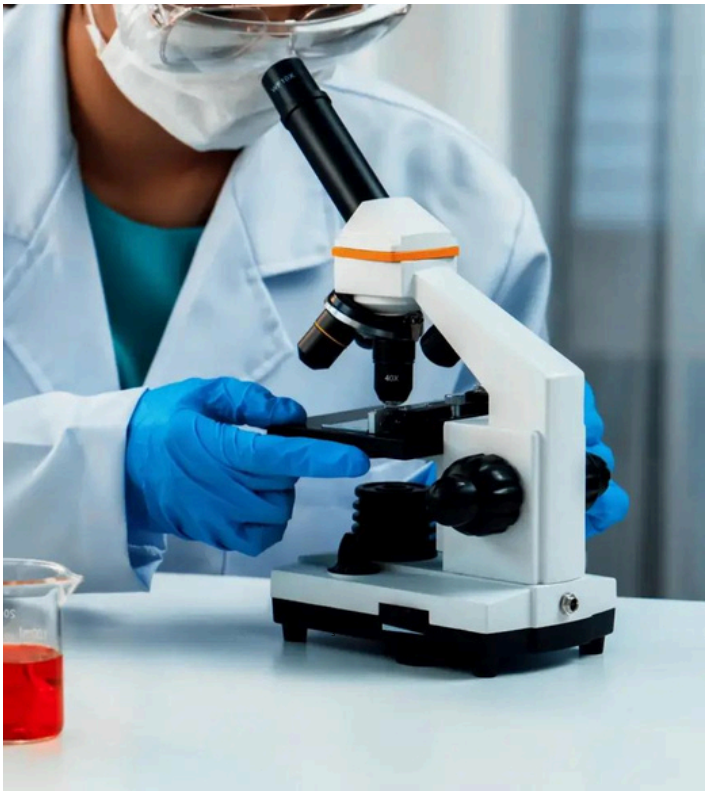
Detailed reporting on population health by underlying cause of death is essential for public health decision-making. Cause-specific mortality estimates and their impact on life expectancy are crucial metrics for assessing progress in reducing death rates, especially after significant mortality events like the COVID-19 pandemic. Analyzing mortality rates and life expectancy over time allows for global and temporal comparisons of death causes, offering insights into their effects on populations.

The COVID-19 pandemic disrupted long-term gains in life expectancy and reductions in leading causes of death, with uneven impacts across different populations.[2] Continue reading here.

.

A NEW GUIDELINE FOR ADVANCED THERAPY FOR MEDICINAL PRODUCTS

The European Medicines Agency (EMA) has released a draft Guideline on quality, non-clinical, and clinical requirements for investigational advanced therapy medicinal products (ATMPs) in clinical trials for public consultation. This guideline outlines the structure and data requirements for clinical trial applications, covering both exploratory and confirmatory trials for ATMPs. It addresses multidisciplinary aspects including development, manufacturing, quality control, and both non-clinical and clinical development. The guideline details requirements for exploratory trials, such as First in Human studies, and confirmatory trials, with a view toward eventual Marketing Authorization Application (MAA).[3]



Feedback on the guideline should be submitted to: AdvancedTherapies@ema.europa.eu The draft guideline is available here.

MODULE 7: LEADERSHIP IN MEDICAL AFFAIRS

The GMDP Academy is pleased to announce the availability of Module 7: Leadership in Medical Affairs. This module is specifically designed for professionals involved in Medicines Development who have aspirations in raising the profile of their role, and will start on September 30, 2024.

Add this course to your portfolio of formal training and develop professional leadership skills so you can leverage the strategic decision-making within your organization.

In upcoming news, we will introduce you to the two chairs of this module, Professor Domenico Bodega and Dr. Kevin Williams. For today, learn more about the program and all related details here.

REFERENCES

1. Committee for Human Medicine Products (CHMP). (2024). Reflection paper on use of real-world data in non-interventional studies to generate real-world evidence. In European Medicines Agency (EMA/CHMP/150527/2024; pp. 2–16). https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-use-real-world-data-non-interventional-studies-generate-real-world-evidence_en.pdf
2. GBD 2021 Causes of Death Collaborators, & Hay, S. I. (n.d.). Global burden of 288 causes of death and life expectancy decomposition in 204 countries and territories and 811 subnational locations, 1990–2021: a systematic analysis for the Global Burden of Disease Study 2021. The Lancet, 403, 2100–2032. https://www.thelancet.com/action/showPdf?pii=S0140-6736%2824%2900367-2
3. Committee for Advanced Therapies (CAT). (2024). Guideline on quality, non-clinical and clinical requirements for investigational advanced therapy medicinal products in clinical trials. https://www.ema.europa.eu/en/documents/scientific-guideline/draft-guideline-quality-non-clinical-clinical-requirements-investigational-advanced-therapy-medicinal-products-clinical-trials-second-version_en.pdf

Thanks for reading!

The GMDP Academy Newsletter is published twice monthly and is compiled by the following:

Medical Editor: Domenico Criscuolo

Media Manager: Whitney English

Editorial Board: Pravin Chopra, Jacob Coots, Honorio Silva, Peter Stonier

Operations Office: Amanda Schmitt, Gustavo Silva, Kit Vale

CONTACT US:

420 Lexington Ave. Ste. 300
New York, NY 10170

(332) 333-2438