GMDP academy
ISSUE 45 • MARCH 29, 2024

EXPLORE MODULE 8: DIGITAL TECHNOLOGY IN MEDICINES DEVELOPMENT WITH GMDP ACADEMY!

Exciting opportunities are on the horizon as GMDP Academy extends a warm invitation to individuals eager to network, explore practical applications of digital tools, and advance their careers within medicines development.

Module 8: Digital Technology in Medicines Development promises a transformative learning experience tailored to professionals seeking to navigate the dynamic intersection of medicines development and digital advancement.

Choose from two flexible date options: April 21 to June 14 or September 23 to November 8. Learn more here.

TABLE OF CONTENTS

UPDATING GUIDELINES FOR HEPATITIS B TREATMENT: EMA CALLS FOR PUBLIC INPUT

The European Medicines Agency has released a concept paper regarding updates to the guideline for evaluating medicinal products designed for treating Hepatitis B, open for public input. This document aims to modernize the guideline for assessing medicinal products intended for Hepatitis B treatment, initially established by CHMP on February 23, 2006, and implemented on September 1, 2006.Recent years have witnessed numerous requests for scientific guidance on novel products and treatment strategies, particularly focusing on achieving functional cures through finite and combination therapies. Additionally, there have been advancements in antiviral and immunomodulatory treatments with distinct mechanisms -

from nucleos(t)ide analogues (NUCs) or peg-interferon alfa 2a (PEG-IFN). Consequently, revising the guideline is imperative to accommodate these advancements and their implications for clinical development programs.[1]

Feedback is welcome until April 30, 2024, through the EU survey. Read the full text here.

RESEARCH MISCONDUCT ON THE RISE: CASES, CONCERNS, AND IMPACT

Allegations of research misconduct have surged in recent times, drawing attention through prominent cases. Notably, accusations of image manipulation at the Dana Farber Cancer Institute have prompted retractions. Furthermore, a comprehensive analysis by Nature revealed a staggering number of retractions in 2023, surpassing 14,000 papers—the highest ever recorded. Alarmingly, more than 8,000 of these retractions were associated with Hindawi, an open-access publisher. Hindawi's owner, Wiley, has attributed this concerning trend to "large-scale systematic manipulation," implicating practices such as paper mills and fraudulent special issues.[2]

Read more here.

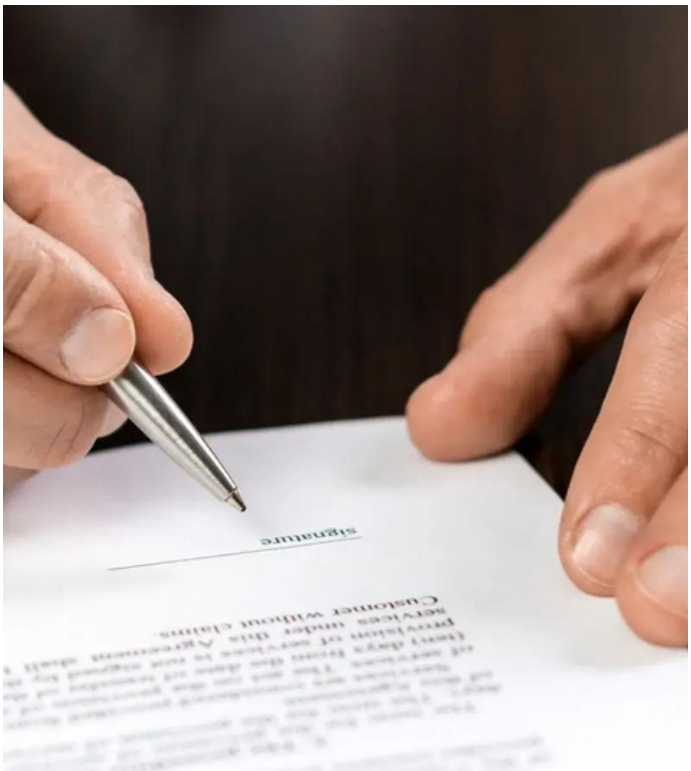
EUROPEAN MEDICINES AGENCY'S PILOT SCHEME SUPPORTS ACADEMIC ATMP DEVELOPERS

After the launch of such in September 2022, the European Medicines Agency (EMA) initiated a pilot scheme welcoming three academic and non-profit organizations developing advanced therapy medicinal products (ATMPs), providing tailored support to guide them through regulatory processes in the European Union (EU) and aiming to enhance their understanding of requirements to facilitate progress towards marketing authorization. The scheme, intended to assist developers addressing unmet medical needs, plans to include two more participants by the end of 2024.

Among the inaugural participants is the Hospital Clínic de Barcelona, developing ARI-0001, a chimeric antigen receptor (CAR) product targeting relapsed/refractory acute lymphoblastic leukemia.

EMA's commitment to supporting non-commercial developers underscores the significance of their contributions to ATMP development, recognizing the challenges they face in navigating regulatory pathways.[3] Read more here.

SIMPLIFYING INFORMED CONSENT: FDA'S INITIATIVE FOR CLEAR UNDERSTANDING



Each day, numerous individuals contribute to scientific research, yet understanding the complexities and implications of participation can be challenging. In response, the U.S. Food and Drug Administration (FDA) and the Office for Human Research Protections have introduced a draft guidance aiming to streamline the comprehension of informed consent forms. Stakeholders, including research sponsors, investigators, and institutional review boards (IRBs) who wish to provide feedback towards refining the informed consent process should review the draft guidance and submit their feedback by April 30, 2024.[4]

Access the full text and draft guideline here.

STREAMLINING ACCESS TO COMPLEX GENERICS: CDER'S OGD AND EMA'S COLLABORATIVE PILOT PROGRAM

In an effort to enhance patient access to complex generic drugs, the Office of Generic Drugs (OGD) at the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have initiated a voluntary pilot program. This program aims to facilitate simultaneous discussions between generic drug applicants and both regulatory bodies. This initiative marks an extension of the existing Parallel Scientific Advice (PSA) program between the FDA and EMA, specifically targeting complex generics or "hybrid medicines" (a term used by EMA to describe medications akin to complex generics).

The progression of complex generic drug development stands as a pivotal aspect-

The progression of complex generic drug development stands as a pivotal aspect of the FDA's mission to provide patients with access to safe, effective, and high-quality generic medications.[5] Read more here.

REFERENCES

1. Clinical evaluation of medicinal products intended for treatment of hepatitis B - Scientific guideline | European Medicines Agency. (n.d.). https://www.ema.europa.eu/en/clinical-evaluation-medicinal-products-intended-treatment-hepatitis-b-scientific-guideline
2. Lancet. (2024). Safeguarding research integrity. The Lancet, 403(10428), 699. https://doi.org/10.1016/s0140-6736(24)00349-0
3. Progress update on pilot for academic and non-profit developers of advanced therapy medicines | European Medicines Agency. (2024, February 8). https://www.ema.europa.eu/en/news/progress-update-pilot-academic-non-profit-developers-advanced-therapy-medicines
4. Office of the Commissioner. (2024, March 1). FDA works to make informed consent easier to understand. U.S. Food And Drug Administration. https://www.fda.gov/news-events/fda-voices/fda-works-make-informed-consent-easier-understand
5. Research, C. F. D. E. A. (2024, February 8). CDER's OGD and EMA's parallel Scientific Advice pilot program for complex Generics works to increase harmonization and bring generic drugs to patients. U.S. Food And Drug Administration. https://www.fda.gov/drugs/our-perspective/cders-ogd-and-emas-parallel-scientific-advice-pilot-program-complex-generics-works-increase

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