GMDP academy
ISSUE 37 • NOVEMBER 10, 2023

RUMOR CONTROL: LEARN AND SHARE FDA FACTS TO STOP THE SPREAD OF MISINFORMATION

The United States Food and Drug Administration (FDA) has consistently aimed to combat misinformation related to health, medical products, and treatments. The rise of medical misinformation, especially in the context of health and medical products and vaccines, has been a growing concern globally. Misinformation can mislead the public, potentially leading to harmful health choices, reduced trust in scientific and medical institutions, and an increase in public health risks.

Read more on the GMDP website here, and go here to access some basic and shareable facts from the FDA.

TABLE OF CONTENTS

PROFESSIONAL IDENTITY AND MEDICINES DEVELOPMENT

Reflections from Academy Alumna: Dr. Dragana Kolarski

DR. DRAGANA KOLARSKI

"While contemplating on development and status of my Professional Identity and Sense of Purpose, I've realized that right now is an excellent moment to pause, look back and ask myself questions about the course of my career. I've just changed positions in my company after 8 years of working in rare diseases and now I am engaged in a different therapeutic area.

Thinking of all the things that lead me to this point, I can't help but remember my childhood and long hours spent with my friends playing Star Trek, always in the role of my favorite character Dr. McCoy (known as Bones), pretending to heal all possible known and imaginary diseases. This perfectly depicted my dreams at the time, being a space traveler, doctor and changing the world. Growing up brought different aspirations, but somehow when it came to deciding what would be my future profession, I had no second thoughts whatsoever – I chose to study medicine. My parents were scientists, but had no connection to medicine, so I had no realistic idea what it meant to be a doctor and work as a physician treating patients. Nevertheless, the more I learned about medicine the more I liked it and recognized it as my true vocation." **Read her complete essay here.**

Dr. Kolarski is a medical doctor specialized in internal medicine. She is currently working as the Internal Medicine Medical Affairs Scientist Lead in Adriatic, Serbia and CBC for Pfizer. She is based in Belgrade, Serbia.

We are thrilled to announce the inaugural Graduation Ceremony of the GMDP Academy, celebrating the remarkable achievements of our students who have successfully completed the Certification in Medicines Development program this academic year.

Save the Date:
Date & Time: 10AM – 11:15AM EST, Tuesday, January 30, 2024
Location: Virtual via Zoom
Click here to register

This pivotal event signifies not just the conclusion of a demanding academic journey but also the continuance of promising careers in the field of medicines development.

The ceremony agenda will feature:

- An enlightening keynote address
- Recognition of our graduates
- Insights from program participants
- Acknowledgements to our esteemed sponsors
- Thought-provoking closing remarks.

The palpable enthusiasm from our academic staff and the graduates guarantees an event brimming with gratitude, introspection, and hopeful anticipation.

We kindly encourage sharing this invitation with colleagues and anyone invested in the future of medicines development. This ceremony is an opportunity for our entire community to come together in celebration of our collective accomplishments.
Pleaqse mark your calendars, register using the provided link, amplify the message on platforms like LinkedIn, and watch out for further updates.

Conversations with the Academy presents:

THE REMARKABLE TRIUMPH OVER HEPATITIS

November 27, 2023, 8:00 AM - 9:00 AM EST

Register to attend

Dr. Ferruccio Bonino
Full Professor of Gastroenterology
Senior Research Associate presso IBB
Pisa, Italy

Dr. Flor H. Pujol
Emeritus and Full Professor
Head of the Laboratorio de
Virología Molecular
IVIC, Venezuela

1

Join us for a captivating webinar delving into 'The Remarkable Triumph Over Hepatitis.' Explore the fascinating journey of battling viral hepatitis, a disease once rampant in Mediterranean countries and Latin America, with no effective treatments in sight. In the early 1980s, the first glimmers of hope emerged with the use of interferon alfa, showing modest yet promising results. However, it would take several more decades of relentless research and innovation to witness the advent of multiple potent antiviral therapies capable of completely eradicating the virus from infected patients. Don't miss this extraordinary success story that has transformed the landscape of hepatitis treatment!

During this insightful event, you can expect to:

1. **Explore the challenges and limitations of early treatment methods, such as interferon alfa, in combating hepatitis.**
2. **Examine the evolution of hepatitis treatment strategies over the decades and the role of relentless research and innovation in achieving breakthroughs.**
3. **Assess the transformative impact of the advancements in hepatitis treatment on the overall healthcare landscape and patient outcomes.**

Register Now

EMA EVENT ANNOUNCEMENT: EUDRAVIGILANCE AND SIGNAL MANAGEMENT INFORMATION DAY

The European Medicines Agency has scheduled an EudraVigilance and Signal Management Information Day for November 21, 2023, from 09:30 to 17:00 CET. This in-person event will take place at the EMA premises in Amsterdam.
This event will provide insights into the ongoing development of the EudraVigilance database and international initiatives influencing it. It will also cover the database's management and maintenance.

Throughout the day, there will be discussions on data protection, the quality of Individual Case Safety Reports (ICSRs), and inspection findings. Additionally, new projects and initiatives, such as compliance reports and the Signal and Safety Analytics project, will be introduced, with direct implications for Marketing Authorization Holders

Furthermore, the event will explore novel methodologies for signal detection and the future potential of utilizing artificial intelligence.

Registration is available until November 17, 2023. Please be aware that space is limited due to room capacity.

Get more information and register here.

CHART YOUR PATH IN MEDICINES DEVELOPMENT CAREER: SUBMIT YOUR APPLICATION NOW

The GMDP Academy, in collaboration with King's College London, is pleased to accept applications for the 2024 cohort of the highly acclaimed Certification in Medicines Development (CMD) program.

Don't miss your chance to become part of a truly unique educational journey in Medicines Development! Join fellow professionals from around the world and advance your career with the 2024 GMDP Academy-King's College London Certification in Medicines Development Program .

Group rates are available for sponsoring organizations. For more information contact admissions@gmdpacademy.org.

Apply Today

ENSURING THE SAFETY AND EQUALITY OF ARTIFICIAL INTELLIGENCE IN MEDICINE

The rapid progress of generative AI, exemplified by Open AI's ChatGPT and its capacity for lifelike conversations and image/video generation, has sparked both interest and concern in its potential applications in healthcare. While AI has demonstrated impressive capabilities in medicine, such as interpreting medical images and driving progress in infectious diseases and molecular medicine, the full potential of generative AI in the field remains largely speculative.

Though initiatives aim to utilize AI for various healthcare tasks, concerns persist around its applicability to diverse datasets, potential errors, privacy breaches, and exacerbation of biases in healthcare access and data representation, all of which contribute to the erosion of patient trust.

The Lancet Oncology recently published an article regarding one of the first randomized controlled trials of AI-supported mammography. However, there are serious risks which must be considered.[1]

EMA REVISES TRANSPARENCY RULES FOR EU CLINICAL TRIALS INFORMATION SYSTEM (CTIS)

The European Medicines Agency (EMA) has implemented updated regulations regarding the disclosure of information on clinical trials submitted through the EU Clinical Trials Information System (CTIS). These enhancements aim to streamline the accessibility of clinical trial data to various stakeholders, including patients and healthcare professionals, in a more expeditious and effective manner.

A notable modification in the new guidelines is the elimination of the deferral mechanism, which previously permitted sponsors to postpone the publication of specific data and documents for a maximum of seven years following the trial's conclusion. This measure was initially implemented to safeguard personal data and commercially sensitive information (CCI)[2]. Continue reading here.

REFERENCES

1. The Lancet, volume 402. August 12, 2023
2. Ema. (2023, October 6). Revised transparency rules for the EU Clinical Trials Information System (CTIS) – European Medicines Agency. European Medicines Agency. https://www.ema.europa.eu/en/news/revised-transparency-rules-eu-clinical-trials-information-system-ctis

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