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COMMUNITY SPOTLIGHT: FLORIN DRAICA ON WHAT HE VALUES ABOUT BEING AN ACADEMY ALUM

We love hearing from our learning community. We extend our gratitude to Florin Draica, US Senior Medical Director for the Pfizer PAXLOVID team for sharing what he valued most about his participation in the Professional Certification in Medical Affairs in Medicines Development from the Academy and King's College London.

Continue reading on page 2 to hear what Florin has to say. Click here to read his entire contribution.

TABLE OF CONTENTS

Florin Draica, MD, CMD, MBA

Florin leads the US HQ PAXLOVID Medical Affairs Team. He is an MD with an MBA in Marketing and IFAPP Certification in Medicines Development. Florin is a Biopharma professional with 20 years of broad experience in various aspects of pharmaceutical medical affairs, medical innovation and operations, marketing and commercial operations, and has had multiple disease area expertise, with responsibilities ranging from country to global. Having had direct experience from prelaunch planning to market and product performance auditing, strategy development and implementation across multiple markets, Florin managed people and teams, including multiple teams in various functions - coordinated marketing teams, including multichannel marketing, sales force, medical, regulatory and drug safety. He also led new business development and coordinated activities in strategic alliances.

"What I appreciated most about the Professional Certification, Medical Affairs in Medicines Development from IFAPP Academy & King's College London in 2019 is that Faculty are senior leaders with such a rich expertise in all areas of R&D, Regulatory and Medical Affairs and how they helped provide an integrative and rewarding education journey. Another key feature of the program was the great opportunity to work along with peer medical affairs professionals from across the globe. Understanding regional differences but also common themes and opportunities helped enhance the learning experience and take it to a new level; I felt I was being part of a truly global group of medical professionals tackling various projects."

GENE THERAPY IN CHINA: PAST, PRESENT, AND FUTURE

Rapid advancements in gene therapy have contributed significantly to the treatments and cures for genetic disorders. In China, there are approximately 200,000 newborn babies each year with genetic disorders, 22% of which are caused by monogenic mutations. Birth defects, endocrine or metabolic diseases, nervous system diseases, and blood system diseases are the four most common genetic disorders. Additionally, gene therapies such as chimeric antigen receptor (CAR) T-cell immunotherapy have been increasingly reported as effective treatments for diseases such as cancer and HIV infection. Globally, China has registered the third most clinical trials for gene therapy.

“The first human gene therapy in China was reported in 1996.

Qiu and colleagues conducted a trial in patients with haemophilia B using an ex-vivo approach, which involved autologous fibroblast cells transduced by a retrovirus that expressed the human Factor IX gene. This approach generated an observable but unsustained therapeutic effect." [1]

Continue reading here.

SAFETY OF MRNA COVID-19 VACCINES DURING PREGNANCY

The use of any drug during pregnancy may be the source of significant anxiety and myriad discussions regarding safety of such. This continued to be the case during the COVID-19 pandemic, where pregnant people were at increased risk of severe illness and death, and there was concern about the safety of the vaccines for pregnant people. Additionally, COVID-19 during pregnancy is associated with increased risk for adverse pregnancy outcomes, such as preterm birth and stillbirth. When mRNA COVID-19 vaccines first became available in December 2020, safety data in pregnancy were limited because pregnant people were excluded from pre-authorisation clinical trials. Lack of data and safety concerns contributed to initially low uptake among pregnant people, which continues to be lower than uptake among non-pregnant females of reproductive age.[2]

Continue reading here.

EMA PUBLISHES CONCEPT PAPER ON PLATFORM CLINICAL TRIALS

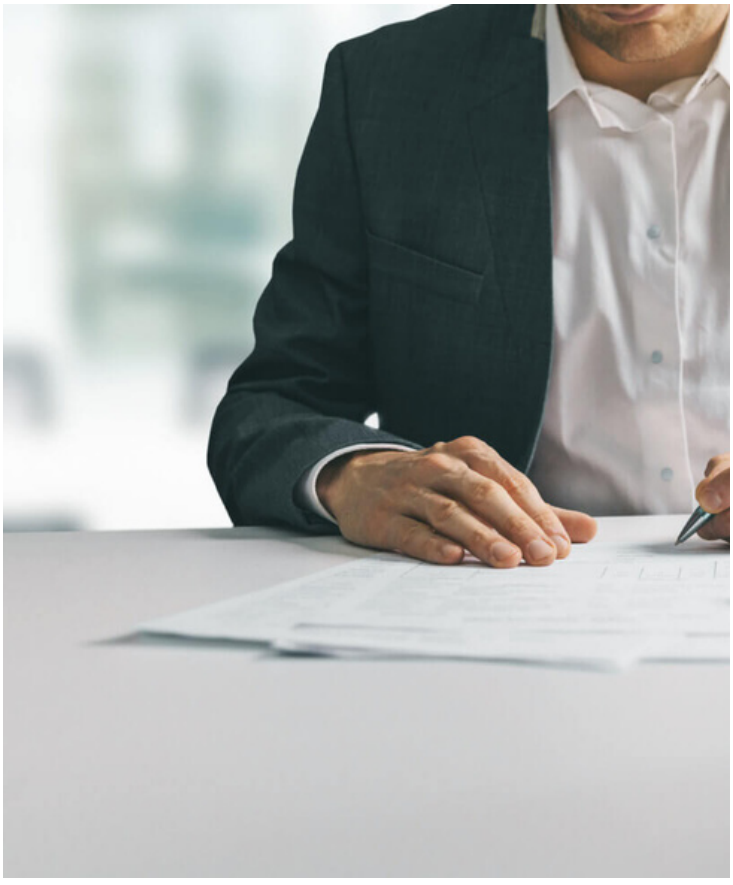
The methodology of clinical trials is continuously evolving, and there has been recent interest in platform clinical trials. Platform trials are a type of randomized clinical trial that allow simultaneous comparison of multiple intervention groups against a single control group that serves as a common control based on a prespecified interim analysis plan. Platform trials are an extension of adaptive multiarm, multistage trial designs that allow for the evaluation of multiple interventions using interim evaluations and the addition of new interventions during the trial.

Considering the frequent use of this study design, the EMA has published a concept paper on platform trials, which have become more common in recent years, for public consultation.

Comments regarding the concept paper should be provided using a dedicated template and sent to MWP@ema.europa.eu by 31 January 2023. The EMA may collect and further process some personal data of stakeholders and interested parties who submit contributions to the consultations.

Continue reading here.

ALTERED IMAGE IN 1999 PAPER RAISES PERIL FOR STANFORD PRESIDENT



New findings of altered images in research co-authored by Stanford University president Marc Tessier-Lavigne add to the weight of allegations against him, according to experts on research misconduct. Stanford announced an investigation into its president following allegations of altered images in four papers co-authored by Tessier-Lavigne over a seven-year period earlier in his research career. A subsequent analysis by Elisabeth Bik, a scientific integrity expert who specializes in identifying manipulated images, found an additional image that raises concern in a paper published in the journal Cell in 1999, two years earlier than the set of papers originally flagged to Stanford.[3]

Continue reading here.

THE LANCET LONG COVID PAPER UNDER INVESTIGATION FOR 'DATA ERRORS'

An early and influential paper on long COVID that appeared in The Lancet has been flagged with an expression of concern while the journal investigates "data errors" brought to light by a reader.

An editorial that accompanied the paper when it was published in January of last year described it as "the first large cohort study with 6-months' follow-up" of people hospitalized with COVID-19. The article has received plenty of attention since then.

Titled "6-month consequences of COVID-19 in-patients discharged from hospital: a cohort study," the paper has been cited nearly 1,600 times, according to Clarivate's Web of Science. There are references to it in multiple documents from the World Health Organization.[4]

Continue reading here.

ARE YOU A PART OF OUR GLOBAL COMMUNITY?

Want to be featured in a future edition of the Academy newsletter? Do you have an update you'd like to share with the IFAPP Academy network? We invite you to share a professional achievement, job transition, or personal milestone and welcome your submissions.

Email your news and updates to community@ifappacademy.org.

SALES OF ANTIBIOTICS FOR ANIMAL USE HAVE ALMOST HALVED BETWEEN 2011-2021

The pharmaceutical industry voluntarily agreed to eliminate animal uses of some classes of antibiotics to reduce the likelihood that resistant bacteria develop and threaten human health.

There are several classes of antibiotics that are used in both humans and livestock production. There is some probability that the continued use of these antibiotics to improve performance of livestock would have sped up resistance in bacteria that infect people. Indeed, cases of individuals being colonized by antibiotic-resistant bacterial strains have been documented. So, there are reasons to be concerned about the potential for impacting human health.

The annual report on the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) shows that, since 2011, European countries have substantially reduced sales of antibiotics for animals. According to data from 25 countries that continuously provided input for the full 2011-2021 period, overall sales of veterinary antibiotics decreased by 47% in this interval, reaching the lowest value ever reported.[5] Continue reading here.

WHY IS HEALTH LITERACY FAILING SO MANY?

Health literacy is vital to good health and well-being. It is fundamental to achieving the Sustainable Development Goals by 2030 and is a crucial tool to deliver universal health coverage. People need to know how to prevent disease and navigate healthcare systems to ensure good health outcomes. However, many are not able to make healthy choices, even in countries with the strongest health systems. Why is this? Traditionally, health literacy has focused on an individual's ability to access, understand, appraise, and use information to maintain good health.

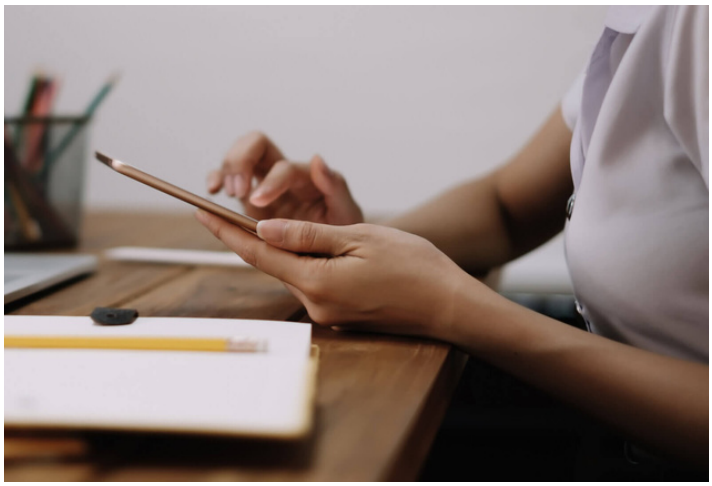
Of course, such knowledge is important. But this approach neglects the societal and structural forces that shape our choices. In many parts of the world, health decisions occur within the family.[6] Continue reading here.

NEWS FROM THE EMA: PUBLIC CONSULTATION FOR THE EVALUATION OF NAS

The European Medicines Agency has published for public consultation a reflection paper on criteria to be considered for the evaluation of new active substance (NAS) status of biological substances.

This document describes the current scientific thinking applied to New Active Substance (NAS) assessment of biological active substances and provides guidance on the elements required to be submitted by applicants to substantiate a NAS claim. Advanced Therapy Medicinal Products (ATMPs) are within the scope of this document.

The different considerations that apply to the NAS assessment of active substances-



in this class of products are presented separately. Chemical active substances and radiopharmaceutical medicinal products are excluded from the scope of this reflection paper.

Comments should be provided using a template available on the EMA website and sent to BWPsecretariat@ema.europa.eu by 31 May 2023.

NEWS FROM ONCOLOGY: UK AWAITS A NEW CANCER PLAN

Many surveys have indicated that current care for oncology patients in the UK is below European standards. Reasons for such include lack of reimbursement from the NHS for new and expensive therapies, among others. According to a recent editorial in the Lancet, "The UK Government was due to publish the next version of the 10-year cancer plan for England in the summer of 2022 with the aim of improving cancer outcomes to match the best in Europe. However, recent political turmoil has resulted in no clear date for when the plan will appear. Given the considerable challenges on health care in the UK, we call on the new Prime Minister, Rishi Sunak, to break this inaction and publish a fully detailed plan as a matter of urgency..."[7]

Continue reading here.

ARE CHATGPT AND ALPHACODE GOING TO REPLACE PROGRAMMERS?

The future of AI is looking smarter and smarter! Artificial intelligence (AI) researchers have been impressed by the skills of AlphaCode, an AI system that can compete with humans in the solving of simple computer-science problems. can often compete with humans at solving simple computer-science problems. Google's sister company DeepMind, an AI powerhouse based in London, released the tool in February and has now published its results in Science. Results indicate that AlphaCode beat about half of humans at code competitions.[8] Continue reading here.

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