GMDP academy
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THE PATIENT ROLE IN MEDICINES DEVELOPMENT: A CONVERSATIONS WITH THE ACADEMY DIGITAL EVENT

As a medicines development professional, you're likely face to face with the crucial role of patient engagement in the creation of new medicines. How is your organization involving patients? What is the path forward as patient engagement becomes increasingly pivotal?

Join us for a captivating conversation about this and more in Conversations with the Academy's latest webinar: The Patient Role in Medicines Development

When & Where: May 3, 2024, 8am to 9am EST

Register now to secure your spot! Click here.

MEET OUR ESTEEMED FACULTY FOR MODULE 8: DIGITAL TECHNOLOGY IN MEDICINES DEVELOPMENT

BRAYDON MCCORMICK

With over two decades of experience as a seasoned entrepreneur and the Founder of Intempio, Braydon is at the forefront of shaping disruptive tech ventures. His strategic insights and passion for HealthTech ensure that you'll gain invaluable knowledge in navigating regulatory landscapes and driving innovation in life sciences.

GILES THURSTON

As a consultancy veteran with over 25 years of experience in software design and development, Giles is dedicated to simplifying technology for real-world applications. His collaborative approach ensures that you'll receive tailored guidance in designing and delivering digital solutions that meet the unique needs of the healthcare sector.

HICHAM NAIM

Dr. Hicham Naim, a Swiss-Moroccan strategist and innovator, brings a wealth of experience from healthcare, life sciences, and consulting industries. His commitment to societal advancement underscores his role in equipping you with the skills to thrive in the ever-evolving landscape of digital health.

MARIE-CLAIRE WILSON

With nearly 15 years of life science consulting experience and a background in clinical medicine, Marie-Claire is uniquely positioned to provide insights into product risk management and improving patient outcomes. Her expertise will be invaluable as you navigate the complexities of medicines development.

MARK DUMAN

Mark Duman's extensive experience spanning clinician roles, management consulting, and patient advocacy makes him a key asset in your journey towards making healthcare more person-centric. His guidance as Chief Patient Officer for MD Healthcare will empower you to drive meaningful change in patient engagement through digital health solutions.

MARK LIGHTOWLER

As the Founder and CEO of Phorix Limited, Mark Lightowler brings a wealth of experience in science-based industries. His leadership in developing global brands ensures that you'll gain insights into the latest digital innovations driving medicines development forward.

SMIT PATEL

Smit Patel's trailblazing work at the intersection of innovative medicine, technology, and healthcare positions him as a leader in the field. His expertise in fostering successful collaborations and scaling digital solutions will equip you with the tools to drive impactful change in healthcare delivery.

Apply now and secure your seat to take the first step towards shaping the future of healthcare through digital technology. Don't miss out. The first offering begins April 21, 2024!

EMA CONFIRMS DECISION ON TRANSLARNA'S MARKETING AUTHORIZATION RENEWAL

After thorough reconsideration, the European Medicines Agency's human medicines committee (CHMP) has upheld its initial decision to decline the conditional marketing authorization renewal for Translarna (ataluren). This medication is prescribed for individuals with Duchenne muscular dystrophy caused by a specific genetic anomaly known as a 'nonsense mutation' in the dystrophin gene, who retain the ability to walk. The original verdict stemmed from a comprehensive re-evaluation of Translarna's pros and cons during the renewal process, concluding that its efficacy remained unverified. In response to a request from the drug's marketing company, the CHMP conducted a re-examination, scrutinizing data from a post-authorization study (study 041) and findings from a comparative analysis of two patient databases.

The CHMP determined that the outcomes from study 041 did not demonstrate the medicine's effectiveness in patients experiencing a gradual decline in walking ability, a group anticipated to derive substantial benefits from Translarna compared to others in the study.[1] Continue reading here.

ADVANCEMENTS IN ALZHEIMER'S TREATMENT: PREPARING EUROPE FOR THE FUTURE

In the near future, Europe faces a significant increase in the population at risk of cognitive impairment due to its rapidly aging demographic. However, there is a ray of hope with the emergence of disease-modifying drugs for Alzheimer's treatment in Europe. Promising treatments like aducanumab, lecanemab, and donanemab have demonstrated the ability to clear amyloid from the brain in the early stages of Alzheimer's, thereby slowing cognitive decline.

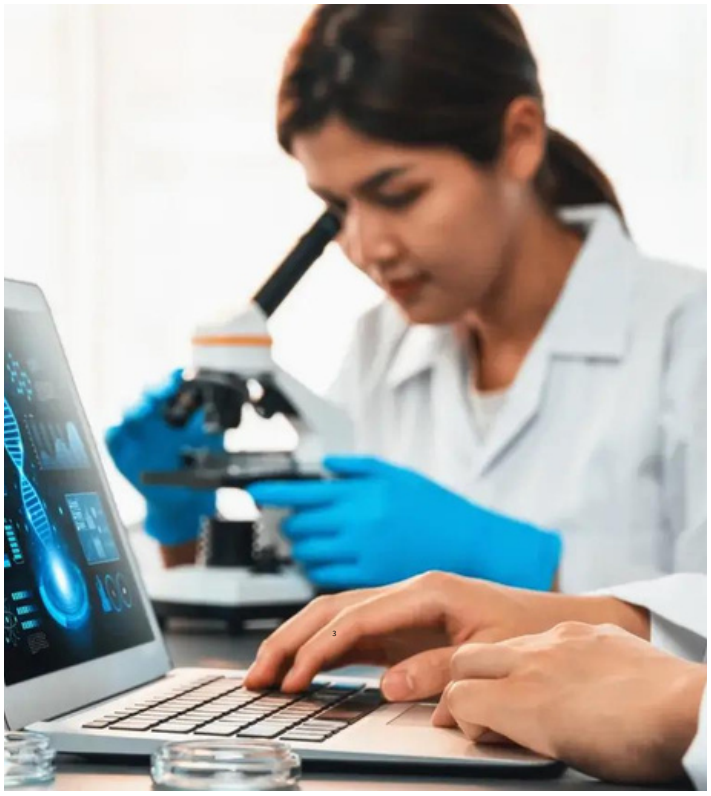
The research on these drugs is progressing rapidly, and if further evidence supports their effectiveness, they could soon become part of clinical practice. Nevertheless, their widespread implementation poses logistical challenges.[2]

Read more here.

UNDERSTANDING POST-VIRAL SEQUELAE: LESSONS FROM COVID-19 AND HISTORICAL PERSPECTIVES

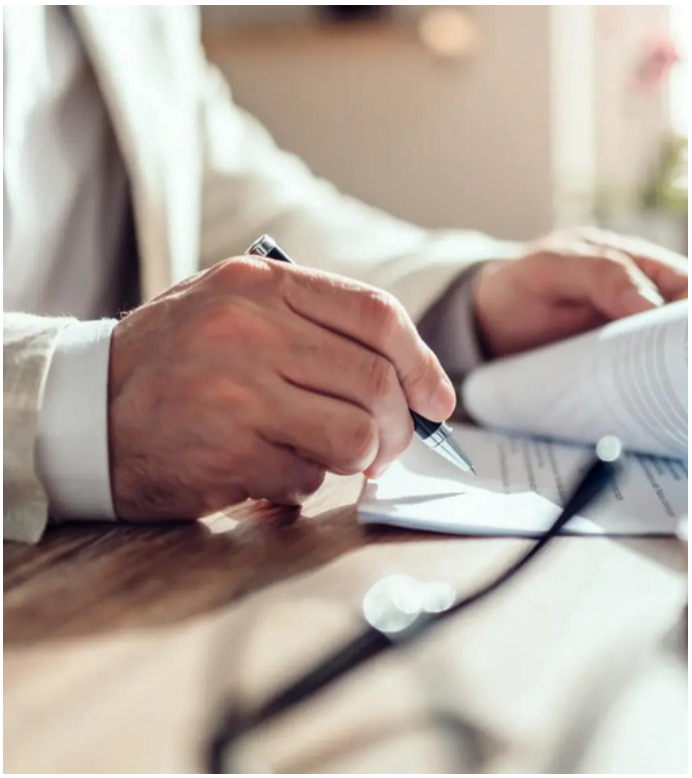
The emergence of COVID-19 in December 2019 marked a significant turning point in global health. Initially identified as a novel respiratory illness in Wuhan, China, by January 7, 2020, the causative agent was identified as SARS-CoV-2, leading to the subsequent classification of the disease as COVID-19. The World Health Organization (WHO) declared COVID-19 a pandemic on March 11, 2020, triggering a worldwide effort to develop vaccines and antiviral treatments. By early 2021, effective COVID-19 vaccines were being rolled out, providing hope for controlling the spread of the virus.

Despite significant progress, the pandemic's impact lingered beyond the cessation of the global health emergency.



On May 5, 2023, WHO declared an end to the emergency status as the mortality rate of COVID-19 approached that of other endemic respiratory viruses like influenza, even in countries with prolonged lockdowns.[3]

ENHANCING ACCESS TO REAL-WORLD DATA: LAUNCH OF TWO PUBLIC CATALOGUES



In an exciting development, the European Medicines Agency (EMA) alongside the Heads of Medicines Agencies (HMA) has introduced two groundbreaking public electronic catalogues aimed at revolutionizing access to real-world data (RWD). This initiative promises to reshape the landscape of medical research by enhancing data discoverability and transparency.

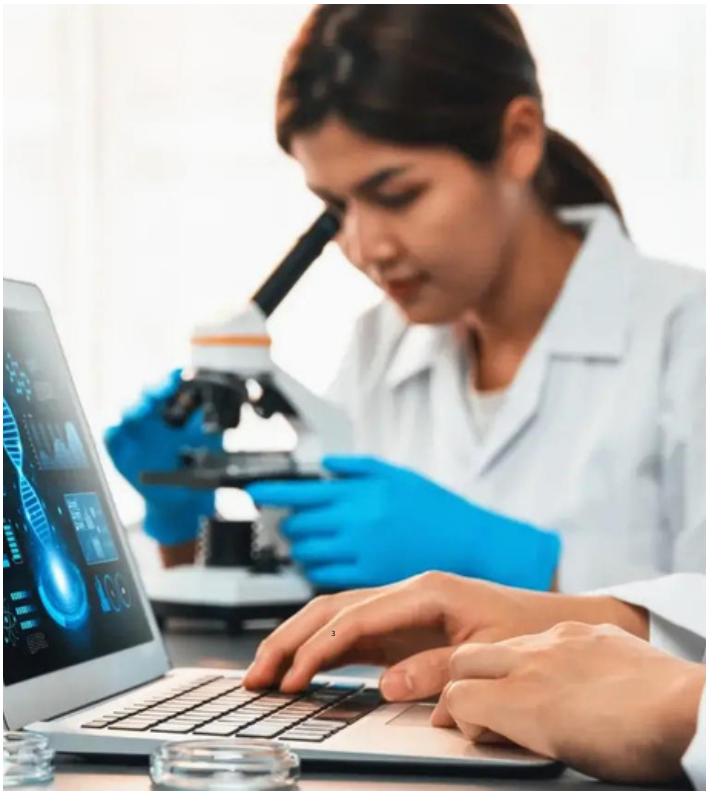
The first catalogue, known as the Catalogue of Real-World Data Sources, serves as a unified replacement for the ENCePP Resources Database. It acts as a centralized repository, consolidating a diverse array of real-world data sources.[4]

Read more here.

UK'S CANCER SURVIVAL RATES COMPARED TO COMPARABLE NATIONS: KEY INSIGHTS FROM 2024

A fresh analysis conducted by the Less Survivable Cancers Taskforce in January 2024 revealed troubling findings about cancer survival rates in the UK compared to similarly affluent nations. Among 33 countries assessed for 5-year survival rates, the UK ranked disappointingly low: 16th for liver cancer, 21st for oesophageal cancer, 25th for brain cancer, 26th for pancreatic cancer, and 28th for lung and stomach cancers. Shockingly, only 16% of patients diagnosed with these six types of cancer in the UK are projected to survive beyond 5 years.

This revelation coincides with alarming reports from 2023 documenting the longest waiting times for cancer treatment in England, marking a nadir in recorded history for patient care.



Furthermore, a study originally published in 2020 in the Annals of Oncology has resurfaced, sparking renewed discourse on cancer survival in Poland. Continue reading here.[5]

EUROPEAN MEDICINES AGENCY SEEKS INPUT ON GUIDELINE FOR EVALUATING COVID-19 TREATMENTS

The European Medicines Agency (EMA) has issued a call for public comments on a concept paper outlining guidelines for the evaluation of antiviral medicinal products and monoclonal antibodies aimed at treating and preventing COVID-19. This initiative comes in response to the persistent challenge posed by SARS-CoV-2, which continues to impact global public health. The proposed guideline seeks to establish a structured approach for assessing the efficacy and safety of these treatments.

Continue reading here.

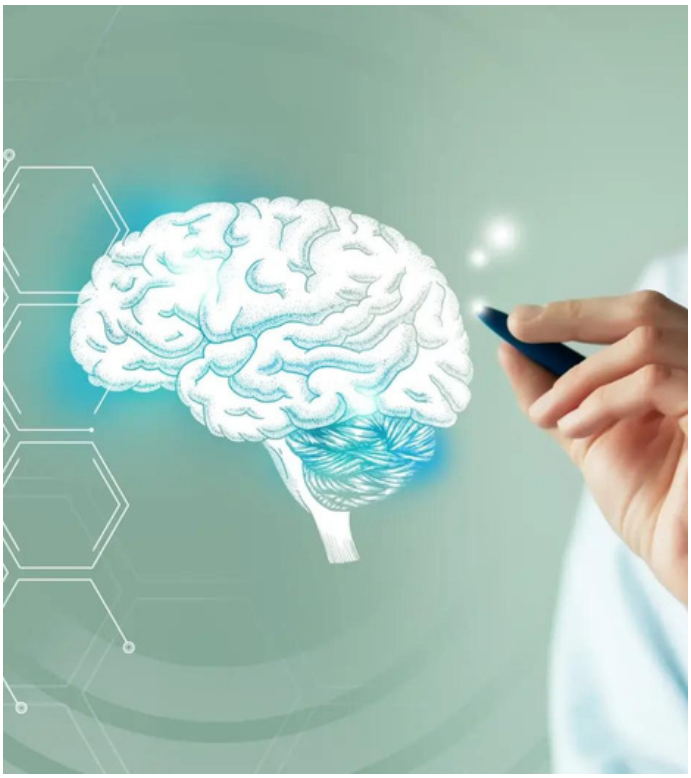
CIOMS REPORT: INTRODUCTION TO MEDDRA LABELLING GROUPING (MLG) STANDARDIZATION (2024)

The CIOMS report Introduction to MedDRA Labelling Grouping (MLG): A standardized approach to grouping adverse reactions in product safety labels (2024) has been released, offering valuable insights into standardizing adverse reaction grouping in medical product labels.

The Medical Dictionary for Regulatory Activities (MedDRA) is a terminology developed by the International Council for Harmonisation (ICH). While it serves as a precise coding system for adverse events in medicines data analysis, its high granularity can hinder the communication of adverse reactions in product labelling for healthcare practitioners.[6]

Continue reading here.

UNDERSTANDING THE GLOBAL BURDEN OF NEUROLOGICAL DISORDERS: NEW INSIGHTS AND URGENT ACTIONS



Neurological disorders are on the rise, affecting a growing number of individuals worldwide, according to new findings from the Global Burden of Disease Study. In 2021, over 40% of the global population, totaling 3·4 billion people, were living with conditions impacting the nervous system, signaling an escalating health crisis.

This updated analysis, conducted by the Institute for Health Metrics and Evaluation (IHME) at the University of Washington, Seattle (WA, USA), in collaboration with the World Health Organization (WHO), expands upon previous research by including 22 additional conditions, such as infectious diseases and neurodevelopmental disorders.[7]

Continue reading here.

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Thanks for reading!

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