GMDP academy
ISSUE 38 • DECEMBER 1, 2023

FDA TRAINING ANNOUNCEMENT: FDA CLINICAL INVESTIGATOR TRAINING COURSE DECEMBER 6-7, 2023

Beginning December 6, 2023, the FDA is hosting its Clinical Investigator Training Course. This course is designed to promote professionalism in the clinical trial industry for individuals involved with submissions to FDA (Investigational New Drug (IND) application, New Drug Application (NDA), Biologics License Application (BLA)), and to familiarize stakeholders with the regulatory and scientific issues involved in the development and approval of medical drugs and biological products.

Follow this link to learn more and register!

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GUIDING THE PATH TO MEDICINES DEVELOPMENT

A Conversation on Academic Learning, Networking, and the Power of a Hybrid Model

JACOB COOTS

Medicines Development professionals have the opportunity to breakdown industry silos and improve outcomes for patients across the globe. It is a collaborative journey, and the Academy's esteemed programs not only impart textbook knowledge but serve to foster the social connections necessary for effective and meaningful adult learning and continuing education.

In our latest Interviews with the Academy segment, Jacob Coots, Director of Operations for GMDP Academy, discusses the importance of networking, learning from peers, and engaging with industry experts, making the hybrid model available through the Academy's programs a transformative learning experience. Click here to view the full segment.

"Our hybrid model allows really, for those two pillars to shine, we have great course content, we have great lectures, we have great transcripts, all of that. But you could do that in another program, right? You could do that in another program, you can go and take an asynchronous course, it's not guided, you're not having any interaction, you don't have industry experts that you can ask questions to, you just basically have a textbook with some exercises. At the GMDP Academy, we really lean into those other two things, we want you to network, we want you to learn from the other students. And we're going to provide you with industry-leading experts that have lived this and are currently living this. They're executives and pharma companies. They are advising the FDA and the EMA. You know, these are people that are doing what our students want to be doing. Right. And so that's the magic of the hybrid model we've created."

- Jacob Coots, Director of Operations, GMDP Academy
CEO, Light Ten

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.

MODELING ANALYSIS: ASSESSING CORRELATION BETWEEN NEUTRALIZING ANTIBODY LEVELS AND PROTECTION FROM SARS-COV-2 INFECTION.

While anti-SARS-CoV-2 antibody kinetics have been described in large populations of vaccinated individuals, we still poorly understand how they evolve during a natural infection of Covid-19 and how this impacts viral clearance. For that purpose, the authors analysed the kinetics of both viral load and neutralizing antibody levels in a prospective cohort of individuals during acute infection with alpha variant. Using a mathematical model, the authors show that the progressive increase in neutralizing antibodies leads to a shortening of the half-life of both infected cells and infectious viral particles.

They estimated that the neutralizing activity reached 90% of its maximal level within 11 days after symptom onset and could reduce the half-life of both infected cells and circulating virus by a 6-fold factor, thus playing a key role to achieve rapid viral clearance.[1]

Read more here.

CHART YOUR PATH IN MEDICINES DEVELOPMENT: 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.

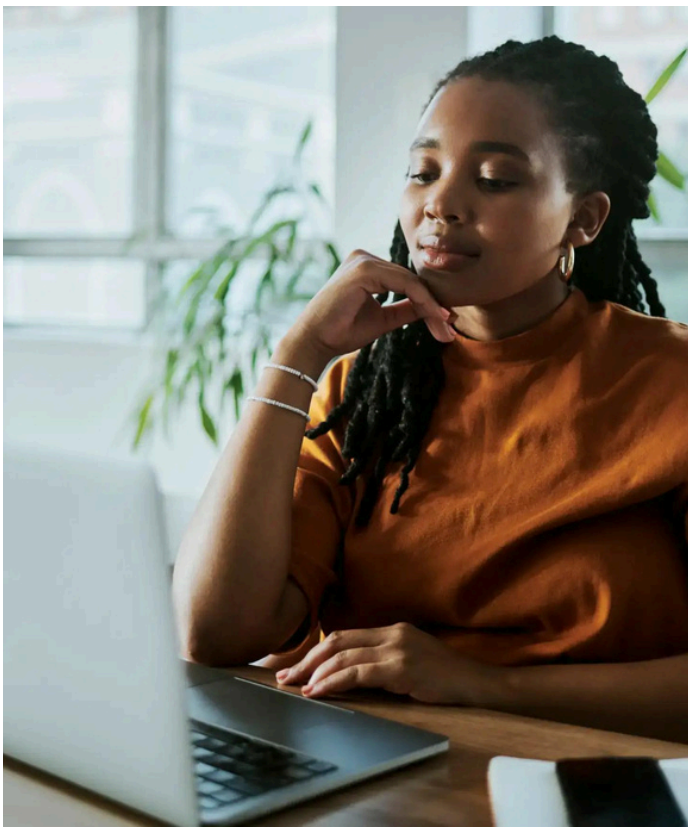
Apply Today

ADDRESSING THE HEALTHCARE BACKLOG IN THE UK: A PLAN FOR RECOVERY & SUSTAINABILITY

The plan for addressing the buildup of patients awaiting elective care in the UK after the COVID-19 outbreak was recently released by the NHS England's Elective Recovery Taskforce. The focus on tackling this backlog holds particular importance for patients dealing with cancer. An initial estimate by a Cancer Research UK report during the early stages of the pandemic indicated that approximately 2.4 million people in the UK were awaiting cancer screening, testing, or treatment. Subsequent analysis from a think tank in 2021 projected that the backlog in the cancer care system might persist until 2033, even with a 5% increase in activity compared to pre-pandemic levels. A recent analysis by the British Medical Association, using data from NHS England, highlighted the mounting backlog across the healthcare sector.

This analysis revealed that the healthcare system is struggling to meet the set timeframes for referrals, screenings, and treatments, thus jeopardizing the achievement of NHS England's[1] cancer recovery targets.[2] Read more here.

EXPAND YOUR KNOWLEDGE WITH ESSENTIAL NEWS FROM EMA



Committed to providing timely and cutting-edge content, we curate essential updates from the forefront of medical advancements. Today, we highlight two crucial publications released by the European Medicines Agency, shedding light on key developments and regulatory insights in the field.

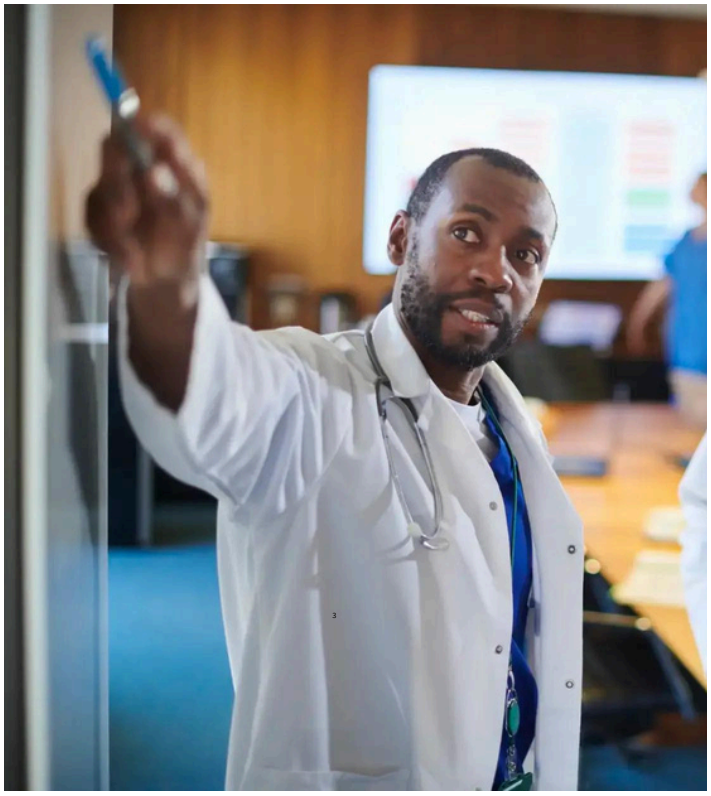
- European Health Union: EU steps up action to prevent shortages of antibiotics for next winter
- 11th Revision of the ENCePP Guide on Methodological Standards in Pharmacoepidemiology

Click here to read more about why these publications are essential to medicines development.

EMA ADVISES AGAINST RENEWAL OF AUTHORIZATION FOR TRANSLARNA IN DUCHENNE MUSCULAR DYSTROPHY TREATMENT.

In the medicines development arena, and to ensure timely access to the latest therapies, particularly for patients with rare diseases, regulatory bodies frequently grant conditional approvals. This allows immediate availability of the new drug to patients, even with limited clinical documentation. However, the applicant is required to submit additional clinical data on safety and efficacy. Here, we discuss a scenario where the subsequent data did not substantiate the marketing authorization, leading to the withdrawal of the new drug from the market.

The European Medicines Agency's human medicines committee (CHMP) has recommended against renewing the marketing authorization for Translarna (ataluren), a drug designed to treat



Duchenne muscular dystrophy in patients who can walk and whose condition is caused by a 'nonsense mutation' in the dystrophin gene. This decision comes after a thorough reassessment of the medicine's benefits and risks.[3] Read more here.

EMA ISSUES WARNING OF FALSIFIED OZEMPIC PENS

Regulatory authorities, in their multifaceted roles, oversee the quality of pharmaceuticals in the market and periodically issue warnings regarding counterfeit drugs—a significant concern demanding heightened vigilance towards the quality and origin of our medications. Recently, the European Medicines Agency (EMA) issued a cautionary notice, revealing that pre-filled pens falsely labeled as the diabetes medication Ozempic (semaglutide, 1 mg, solution for injection) have been discovered at wholesalers in the EU and the UK. These mislabeled pens, featuring German labels, originated from wholesalers in Austria and Germany.[4]

Read more here.

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Thanks for reading!

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