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EMA CALLS FOR FEEDBACK: DRAFT GUIDELINES ON PHAGE THERAPY FOR HUMAN MEDICINAL PRODUCTS TO COMBAT ANTIBIOTIC RESISTANCE

The European Medicines Agency (EMA) has opened a public consultation on a "concept paper on the development and manufacture guidelines for human medicinal products tailored to phage therapy." This initiative aims to establish a scientific framework for the pharmaceutical development and manufacturing of bacteriophage medicinal products, specifically for treating or preventing bacterial infections in humans. Stakeholders and interested parties are encouraged to provide comments by March 31, 2024, using the EU survey form.

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COMPARING TUBERCULOSIS TREATMENT STRATEGIES: INSIGHTS FROM AN ADAPTIVE TRIAL

The standard treatment for tuberculosis typically involves a 6-month regimen based on rifampin, but the efficacy of shorter initial treatment strategies remains uncertain.

In a recent study published in the New England Journal of Medicine, in an adaptive, open-label, noninferiority trial, participants with rifampin-susceptible pulmonary tuberculosis were randomized to receive either standard treatment or an 8-week regimen followed by extended treatment and monitoring for relapse.

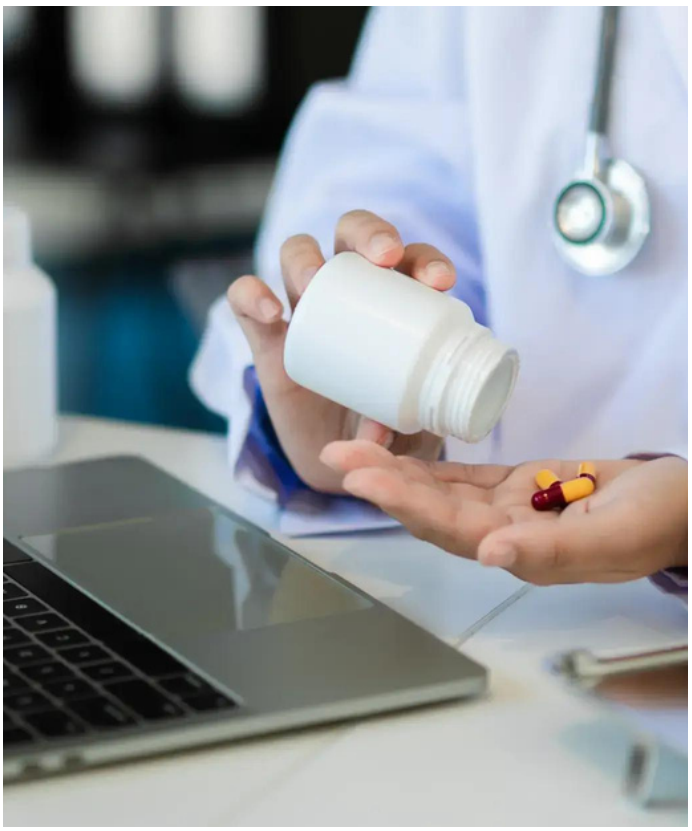
The study evaluated four strategy groups, focusing on initial regimens of rifampin-linezolid and bedaquiline-linezolid.

Results showed that while the bedaquiline-linezolid strategy was noninferior to standard treatment, the rifampin-linezolid strategy did not meet noninferiority criteria.[2]

Additionally, the bedaquiline-linezolid strategy demonstrated a shorter treatment duration without significant safety concerns.[1]

Read more here.

EMA RECOMMENDS SUSPENSION OF GENERIC MEDICINES TESTED BY SYNAPSE LABS FOLLOWING DATA IRREGULARITIES



The European Medicines Agency's human medicines committee (CHMP) has advised suspending the marketing authorizations of several generic medicines tested by Synapse Labs, a contract research organization located in Pune, India. This decision comes after a Good Clinical Practice (GCP) inspection revealed irregularities in study data, deficiencies in study documentation, and shortcomings in the computer systems and procedures for managing study data. These findings have raised serious doubts about the accuracy and dependability of data from bioequivalence studies conducted at the CRO. Bioequivalence studies are conducted to demonstrate that a generic medicine releases the same amount of active substance in the body as the reference medicine.[2]

Read more here.

MULTIFACETED INTERVENTION REDUCES POSTPARTUM HEMORRHAGE RISKS: FINDINGS FROM A CLUSTER-RANDOMIZED TRIAL

Timely detection and treatment of postpartum hemorrhage are critical to prevent complications and fatalities. Utilizing a blood-collection drape can facilitate objective and early diagnosis, while addressing delays or inconsistencies in implementing effective interventions through a treatment bundle.

A recent study published in the New England Journal of Medicine conducted an international, cluster-randomized trial to evaluate a multicomponent clinical intervention for postpartum hemorrhage in patients undergoing vaginal delivery, which included a calibrated blood-collection drape for early detection of hemorrhage and first-response treatments.

Results showed that Early detection and bundled treatment led to improved outcomes in patients undergoing vaginal delivery.[3] Read more here.

RISING PREVALENCE AND UNMET NEEDS: HEART FAILURE WITH PRESERVED EJECTION FRACTION IN OBESITY

The prevalence of heart failure with preserved ejection fraction is on the rise and is linked to significant symptom burden and functional limitations, particularly in individuals who are obese. Currently, there are no approved treatments specifically aimed at addressing heart failure with preserved ejection fraction related to obesity.

A recent study published in the New England Journal of Medicine aimed to evaluate the efficacy of semaglutide in managing heart failure with preserved ejection fraction (HFpEF) in individuals with obesity. A total of 529 patients[9] with HFpEF and a body mass index (BMI) of 30 or higher were randomly assigned to receive either once-weekly semaglutide (2.4 mg) or a placebo for 52 weeks.[4] Read more here.

DEEP LEARNING UNVEILS PROMISING ANTIBIOTICS: MIT'S BREAKTHROUGH AGAINST MRSA

MIT researchers, leveraging deep learning technology, have uncovered a breakthrough in combating a drug-resistant bacterium responsible for over 10,000 annual deaths in the United States using antibiotics. Published in Nature, their study reveals a new class of compounds capable of eliminating methicillin-resistant Staphylococcus aureus (MRSA) in laboratory settings and in vivo mouse models.

Significantly, these compounds exhibit minimal toxicity towards human cells, positioning them as promising candidates for drug development. The study's pivotal advancement lies in the researchers' ability to discern the underlying factors driving the deep-learning model's antibiotic efficacy predictions.

This insight holds promise for the design of enhanced drug therapies surpassing those initially identified by the model.[5] Read more here.

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Thanks for reading!

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