

## ARTIFICIAL INTELLIGENCE, MACHINE LEARNING, AND BIOLOGICAL PRODUCTS

Artificial Intelligence (AI) involves machine-based systems that make predictions, recommendations, or decisions, influencing environments based on human-defined goals. Utilizing both machine and human inputs, these systems perceive and analyze environments, create models, and generate actionable options through automated analysis. A subset of AI, Machine Learning (ML), focuses on training algorithms to enhance task performance using data. The Center for Biologics Evaluation and Research (CBER) has been actively participating in public workshops and discussions led by the FDA and other organizations to explore AI/ML applications in biologics. This involvement aims to develop a regulatory framework that ensures the safe and responsible use of AI/ML while fostering innovation. Keep reading [here](#).<sup>1</sup>

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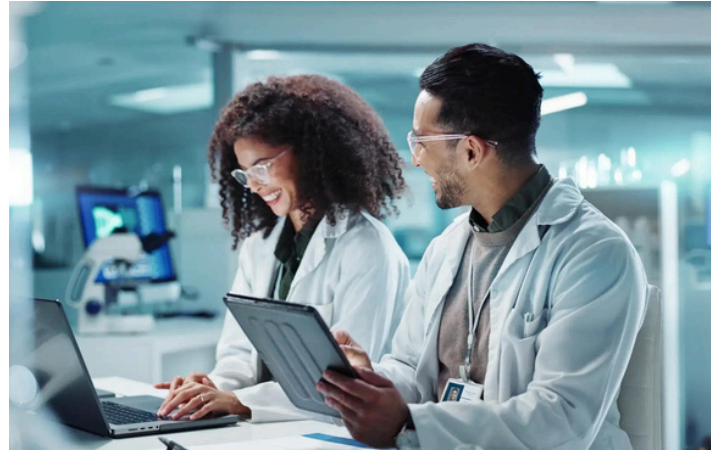
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## THE FDA APPROVES THE 50TH BIOSIMILAR, IN A CONTINUOUS EFFORT TO SUPPORT PATIENTS.

The Biologics Price Competition and Innovation Act of 2009 (BPCI Act) established a pathway for the U.S. to approval biosimilars, which are highly similar to FDA-approved biologics with no clinically meaningful differences. Biologics are expensive treatments, and FDA biosimilar approval can promote competition, lower costs, and increase patient access to therapies. The recent approval of the 50th biosimilar by the FDA indicates a significant increase in biosimilar availability, benefiting patients with various chronic and severe illnesses such as rheumatoid arthritis, cancer, diabetes, and more.



Biosimilars are now approved for 15 different reference biologics, demonstrating their growing impact on healthcare access.<sup>2</sup>

Continue reading [here](#).

## MEASLES VACCINATION IS A MUST!



Measles is an extremely contagious respiratory disease caused by a virus and remains common worldwide. The U.S. FDA-approved vaccines for measles are safe and effective, offering lifelong protection to most people who receive the recommended two doses. Despite this, measles outbreaks still occur in the U.S. due to global increases in measles cases, with unvaccinated individuals bringing the virus into the country, and its spread among unvaccinated communities. Before the vaccination program started in 1963, millions in the U.S. contracted measles annually, resulting in hundreds of deaths, thousands of hospitalizations, and numerous cases of encephalitis. The widespread use of vaccines has reduced measles cases by 99% in the U.S.<sup>3</sup> Continue reading [here](#).

## THE IMPACT OF HAVING A HOUSE ON PEOPLE'S HEALTH

This editorial highlights the critical link between housing and health, dating back to a letter in *The Lancet* from 1922. Despite housing being recognized as a fundamental human right, over 1 billion people lived in unhealthy housing conditions in urban slums in 2022, a figure expected to triple by 2050. Development Goal target was planned to ensure access to adequate housing by 2030, but progress is slow.

Unhealthy housing is associated with poor health outcomes, including respiratory diseases, cardiovascular disease, cancer, and mental health disorders. Vulnerable populations are disproportionately affected, perpetuating health inequities. Governments often fail to prioritize housing, citing financial constraints and lacking political will. However, initiatives like Finland's Housing first approach demonstrate the benefits of long-term investment in housing.



The text emphasizes a rights-based approach and calls for urgent action to address homelessness and inadequate housing worldwide.<sup>4</sup> Read more [here](#).

## CANCER INCIDENCE SHOWS A SIGNIFICANT GLOBAL INCREASE



Projections from various reports regarding the global rise in cancer incidence and mortality highlight important data on breast cancer and prostate cancer. By 2040, breast cancer is expected to surpass 3 million new cases annually, with the greatest increase in low and middle-income countries. Similarly, prostate cancer is projected to increase to 2.9 million new cases annually by 2040.

The text also highlights findings from a study examining cancer incidence in people under 50, showing a significant rise in diagnoses in this age group. Factors contributing to this rise include genetic predisposition, environmental factors, obesity, physical inactivity, unhealthy diet, smoking, and alcohol consumption.<sup>5</sup> Keep reading [here](#).

## CONTINUOUS ATTENTION IS PAID TO COVID INCIDENCE AND VACCINE UPDATES

International regulators, in collaboration with the WHO, have released a report detailing the outcomes of a workshop focused on COVID-19 vaccine strain updates. The report emphasizes that currently authorized vaccines remain effective in preventing severe illness and death from COVID-19, but their protection diminishes over time and with the emergence of new SARS-CoV-2 variants. Therefore, updating vaccine compositions regularly is crucial.

The meeting report outlines key regulatory considerations for updated COVID-19 vaccine compositions and discusses data requirements to support the approval of strain changes. Participants also examined virus evolution and circulation in various regions worldwide.



Conclusions from the workshop include plans to establish a structured process, coordinated by international regulators and the WHO.<sup>6</sup> Read more [here](#).

## AVIAN INFLUENZA: A NEW PANDEMIC ON THE HORIZON?



This publication discusses two cases of human infection with highly pathogenic avian influenza HPAI A(H5N1) virus reported in Viet Nam and Texas, USA, respectively. The Viet Nam case resulted in death following exposure to infected birds, while the Texas case, linked to a dairy farm outbreak, only caused mild illness. While human-to-human transmission wasn't detected, the spread of the virus to cows and subsequent human infection raises concerns.

Since its discovery in China in 1996, HPAI A(H5N1) has evolved into multiple genetic clades, causing sporadic human infections but no sustained human transmission.<sup>7</sup>

Keep reading [here](#).

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## 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