



## META TRAINED AN AI ON 48M SCIENCE PAPERS. IT WAS SHUT DOWN AFTER 2 DAYS

Much credit is given to Artificial Intelligence (AI), and rightfully so. Algorithms formulated by artificial intelligence have provided a great deal of insight into simplifying future tasks in scientific activities. However, a recent article provides us with a real-life example of potential mistakes from the incorrect application of AI and suggests reliance on such may be prematurely optimistic.

Click [here](#) to read the full article.<sup>1</sup>

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## NEWS FROM THE EMA: RELEASE OF NEWSLETTER 162

The European Medicines Agency distributed the September/October newsletter which reports information about new drug approvals (Covid-19 vaccines, antivirals, cancer, cardiovascular, dermatology, diabetes, gynecology & obstetrics, hematology, HIV, immune system, metabolic disorders, nephrology, nervous system, ophthalmology, respiratory system, rheumatology).

It also reports on the scientific activities of the committees and working parties. There are also posted two draft guidelines for the development and manufacture of synthetic peptides and oligonucleotides.



These guidelines are open for consultation until December 20, 2022.

Continue reading [here](#).

## ASPIRIN AND HELICOBACTER PYLORI INTERACTION



Aspirin is by far the largest used drug all over the world, assumed in billions of doses every year. That's why any news regarding the safety of aspirin must be given great attention, as it can have a significant global impact.

“The efficacy of aspirin in the prevention of cardiovascular disease needs to be balanced against the associated increased risk of bleeding, especially of gastrointestinal origin, which is the most common source. There is an urgent need to reduce bleeding events both in primary cardiovascular disease prevention, where the risk-benefit relationship is being questioned, and in secondary cardiovascular disease prevention, where the benefits exceed the bleeding risk, but aspirin is often used in combination with other antiplatelet drugs, which increases the risk.”<sup>2</sup>

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## NEW FEDERAL INCENTIVES FOR DIVERSITY IN CLINICAL TRIALS

Clinical trials are not always an accurate representation of patient populations. In fact, clinical trials often have a very long list of inclusion and exclusion criteria wherein the aim is to select a uniform cohort of patients, but an unintended consequence of such is that this criterion inevitably creates a group that is not an accurate representation of real-world patient populations. Both regulators and sponsors are aware of this, and in fact, recent years have seen a greater emphasis on RWE (real-world evidence) data, usually collected after the marketing authorization of any new drug.

A recent article in the New England Journal of Medicine highlights the importance of enrolling a wider, more diverse patient population in Phase III trials which will be submitted



to regulatory authorities for any future NDA approval. Of note, the new legislation requires these data to be collected before, and not after, the marketing authorization has been granted.<sup>3</sup>

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## INDONESIA BANS ALL SYRUP MEDICINES AFTER THE DEATHS OF 99 CHILDREN



As Medical Affairs professionals, we know that quality is a central component of drug development and manufacturing and remains central throughout the entirety of the development and manufacturing processes. Unfortunately, quality controls in place at manufacturing plants sometimes lack rigidity and oversight, and incidents impacting patient safety may occur. This is the case for hundreds of children who passed away in Gambia and Indonesia. The deaths of nearly 100 children in Indonesia, weeks after a cough syrup in Gambia was linked to the deaths of nearly 70 children, prompted Indonesia to suspend sales of all syrup and liquid medications in the country.<sup>4</sup>

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## LESSONS FROM THE HPTN 071 (POPART) TRIAL

Much of the gradual decline in HIV over the past decade has been attributed to expanded coverage of antiretroviral therapy (ART). An increasing number of people living with HIV are on ART and are virally suppressed, therefore unable to transmit the virus to their partners. Universal testing and treatment have been proposed as a key strategy to increase ART coverage in an attempt to achieve steeper reductions in HIV incidence. This strategy involves wide-scale delivery of HIV testing at the community level, accompanied by effective linkage to care and support for ART adherence. The HPTN 071 (PopART) trial was the largest of four community-randomized trials that were conducted to evaluate the effect of the universal testing and treatment strategy.



The study was performed in Zambia and South Africa, during from 2013-2018. Patients were randomized into 3 arms.<sup>5</sup>

Continue reading [here](#).

## WHAT COVID-19 HAS TAUGHT THE WORLD ABOUT ETHICS



“The Covid pandemic has posed substantial challenges to societies and health systems globally. Many of these challenges have been technical, such as the development of effective vaccines and therapies. The challenges that have proven most vexing and controversial, however, involve determining the “right” course of action on a number of critical issues: how to allocate scarce vaccines, whether to introduce mask and vaccine mandates, whether to restrict travel, and whether to intentionally infect research participants in order to test vaccines, to name a few. The “right” decision in these cases is neither a technical matter nor resolvable by additional evidence; rather, it requires value judgments and, thus, ethics.”<sup>6</sup>

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# 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](mailto:community@ifappacademy.org).



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Thanks for reading! The IFAPP Academy Newsletter is published bi-monthly and is compiled by the following:

Medical Editor: Domenico Criscuolo

Media Manager: Whitney English

Editorial Board: Pravin Chopra, Jacob Coats, Jean Ferreira, Gustavo Kesselring, Honorio Silva, Peter Stonier

Operations Office: Haley Loving, Amanda Schmitt, Gustavo Silva, Kiet Vo

## CONTACT US:



420 Lexington Ave. Ste. 300  
New York, NY 10170

(332) 333-2438