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DENGUE...A NEW THREAT?

Infectious diseases represent a continuous threat for global health. Dengue has all the features to be the next worry: in 2024, Dengue cases have reached a record high, with over 10 million cases reported globally by July 23 across 176 countries, primarily in the Americas. This surpasses the record set in 2023, with more than 24,000 severe cases and 6,508 deaths reported so far. Dengue, caused by four related viruses, has seen a tenfold increase in cases over the past 20 years.

Many cases are asymptomatic or mild, but fatality rates rise during outbreaks.[1] The World Health Organization (WHO) has classified Dengue as a grade 3 emergency, and upcoming monsoons are expected to further increase cases.[1] Read more here.

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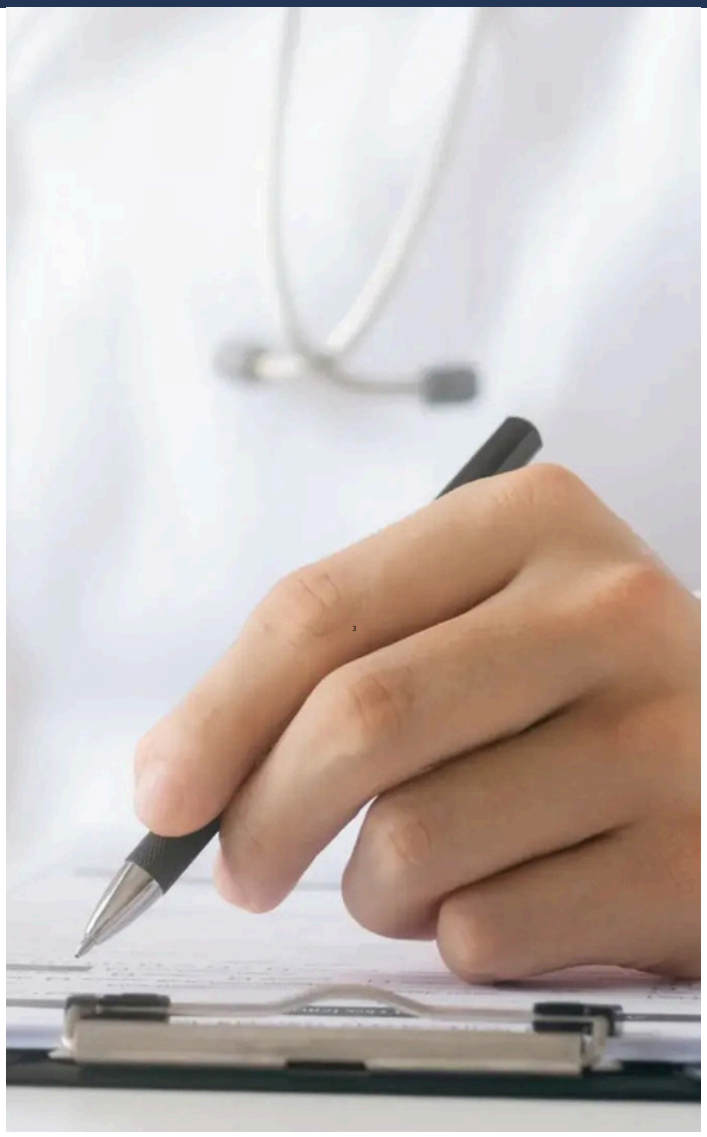
NEW GUIDELINE FOR THE DOSAGE SELECTION OF ANTICANCER DRUGS



Real-World Data (RWD) are today considered one of the best and most reliable sources of information about the use of drugs, as they are collected during the routine way medicines are prescribed and used in everyday clinical settings. The EMA report on Real-World Data (RWD) is of particular interest to regulators, who look at these data with great attention and scrutiny, as they frequently signal unusual adverse reactions or emerging safety concerns.

For this reason, the European Medicines Agency (EMA) has published its second report on the use of Real-World Data (RWD) in scientific studies, fulfilling the Big Data Steering Group's workplan for monitoring and optimizing medicine use. This report, covering the period from February 2023 to February 2024, highlights the significant progress of DARWIN EU, which officially entered its operational phase during this time.[2] Read more here.

DEFINING "SERIOUS" IN PRENATAL TESTING AND REPRODUCTIVE GENETICS

The concept of a "serious" genetic condition is frequently used in clinical settings and policies to regulate the use of reproductive genomic technologies, yet it lacks clear definition and consistency in its application. This article highlights the need for a common understanding of "serious" in the context of prenatal testing and reproductive genetics.

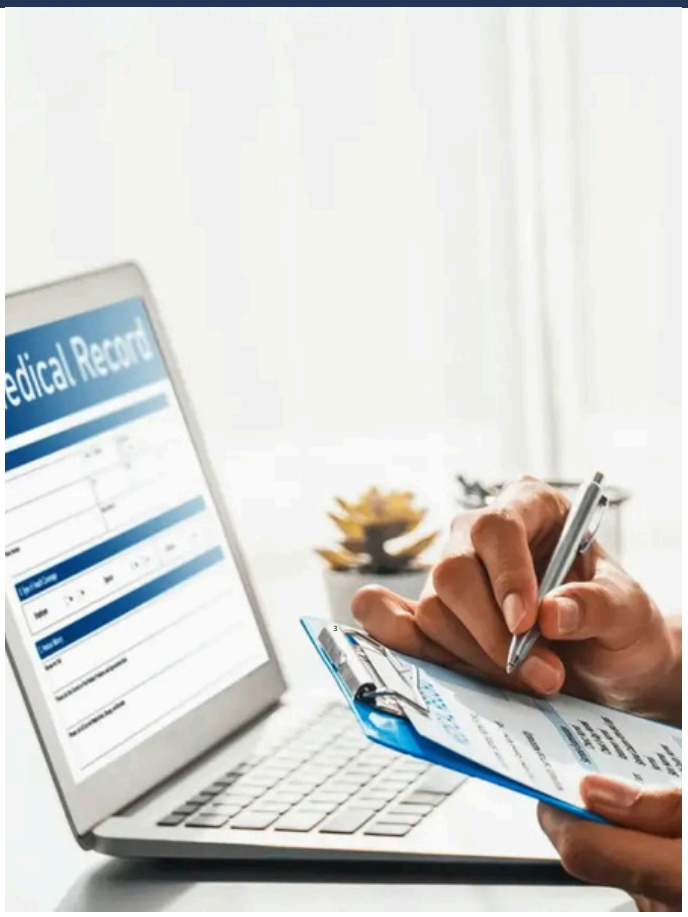
Key distinctions include tensions between clinical care and public health, the effects of labelling a condition as serious, and differing perceptions of quality of life.[3]

Read more here.

NEW GUIDELINE ON DECENTRALIZED CLINICAL TRIALS

Decentralized Clinical Trials had a significant push during the COVID-19 pandemic, as many activities performed in hospitals had to be moved somewhere else, mainly at the patients' homes. The advantages of this shift are so obvious that, at the end of the pandemic, many activities remain decentralized: but of course, both sponsors and Investigators need some guidance.

Therefore, the FDA has released final guidance on conducting clinical trials with decentralized elements, providing recommendations for incorporating remote activities like telehealth visits and local healthcare provider visits. The guidance applies to trials involving drugs, biological products, and devices, and emphasizes that regulatory requirements are the same for decentralized and traditional trials.



Continue reading here.[4]

EMA SEEKS PUBLIC INPUT ON CARDIOVASCULAR SAFETY GUIDELINES FOR ONCOLOGY MEDICINES

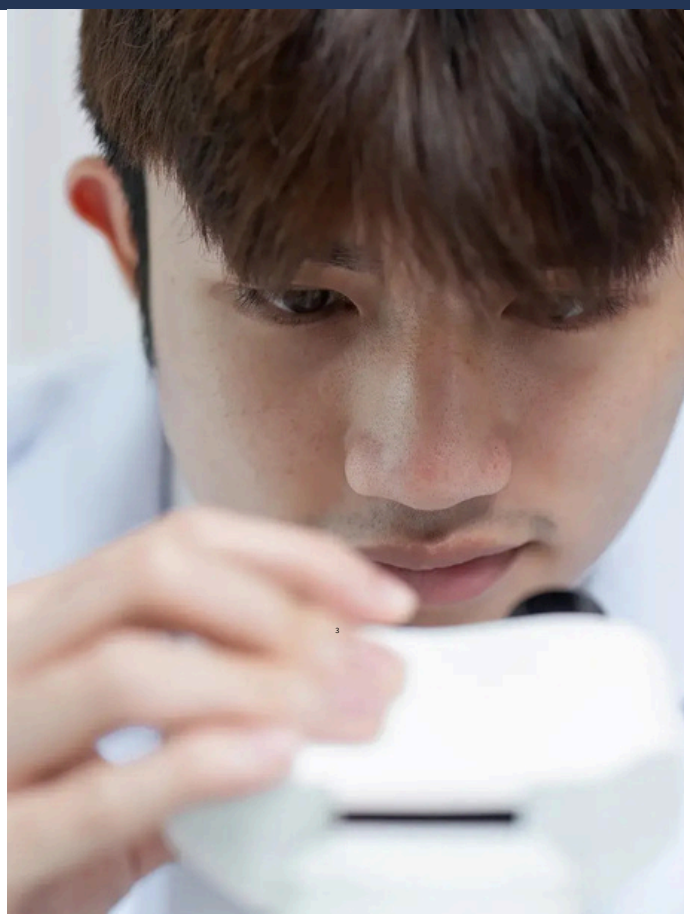
Cardiovascular safety is a very important aspect in the development of many new medicines, and this issue is very important during the development of new oncological therapies. For this reason, the EMA has released a Concept Paper for public consultation regarding the need for a reflection paper on assessing cardiovascular safety in oncology medicinal products.

While a 2016 Reflection Paper focused on cardiovascular safety in vascular and metabolic diseases, this new initiative aims to address oncology-specific considerations.[5] Read more here.

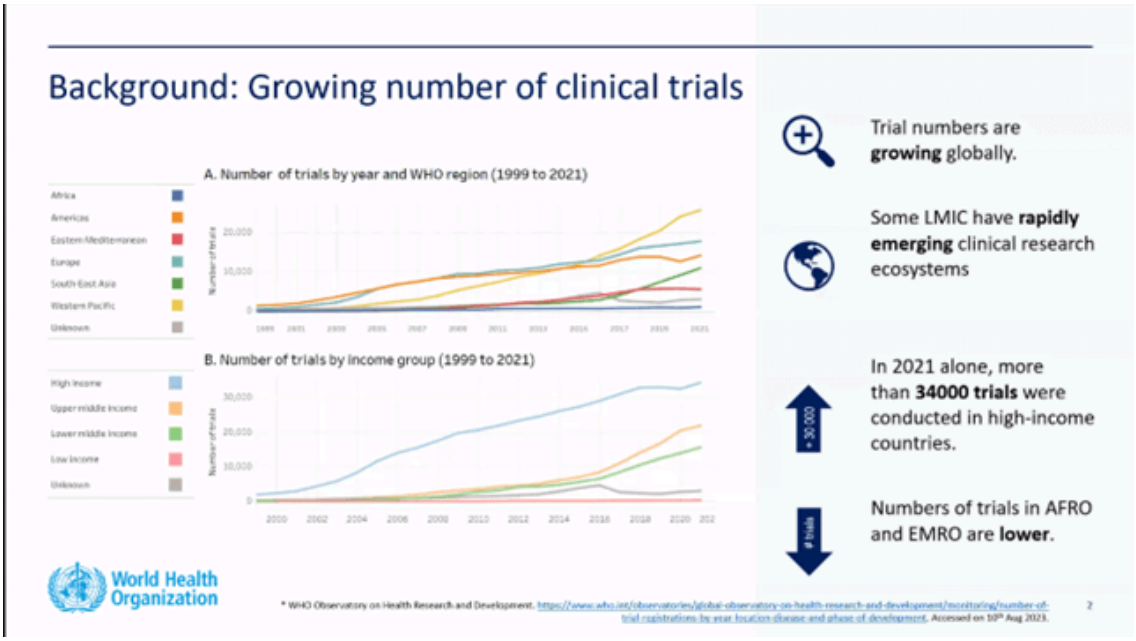
QUALITY ISSUES IN CLINICAL TRIALS: A NEW GUIDELINE

Clinical trials are now a global activity, as you can appreciate by one slide presented during a recent WHO webinar and reported here. The WHO developed a guideline focusing on the most critical issues which can be faced in implementing new clinical trials in various regions of the world.

The new guideline was presented during a webinar held on September 25 and attended by more than 3000 professionals from all over the world: there were several contributions from various authors who underlined the importance of gender equity, attention to rare diseases, but above all, the importance to plan for well designed clinical studies, in order to obtain meaningful results.



Read the new guideline here and view the graphic below.[6]



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Thanks for reading!

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