UNIVERSITIES ALLIED FOR ESSENTIAL MEDICINES

WHO Expert Committee on Selection and Use of Essential Medicines Open Session: UAEM Statement on Clinical Trials Transparency

The ongoing COVID-19 pandemic has repeatedly illustrated the importance of publishing clinical trial data. The pandemic has demonstrated that clinical trial data crucially informs the global community's response to emerging health crises by informing clinical and regulatory decision-making. As our understanding of the virus is rapidly evolving, transparency allows providers to make better-informed decisions about patient care to protect communities that have been disproportionately impacted. Universities Allied for Essential Medicines (UAEM) calls on research universities and other clinical trial sponsors to publish all clinical trial data in a public database that is accessible to all.

Transparency in clinical trials is key to ensuring the safety and efficacy of essential lifesaving medicines, vaccines, and medical devices. Complete and timely registering and reporting of clinical trial results during the research and development process allows for full transparency in outcomes, thereby preventing the duplication of studies and enabling providers to make informed decisions about patient care and treatment. Transparency in reporting will enable researchers to fine-tune future studies, identify unmet medical needs amongst specific populations, and proactively address the risks and benefits of novel health technologies. Clinical trial transparency can also influence the way future research is conducted; for instance, by informing critical decisions around study design, patient recruitment, risk assessment, and funding. Moreover, accurately reported clinical trial results remain the best way for researchers, policymakers, and the public to see that drug and vaccine development is progressing in a safe and trustworthy manner – a feat that corporate press releases alone simply cannot achieve.

In the United States, clinical trial sponsors, such as universities and pharmaceutical and medical device corporations, are legally mandated to report results from interventional clinical trials that are subject to the U.S. Food & Drug Administration Amendments Act of 2007 (FDAAA). This law requires that sponsors report all trial results, even negative and null results, to the ClinicalTrials.gov database within one year of the study's completion. Despite this legal and ethical obligation, about 27% or 2,700 of trial results remain unreported. While non-compliant research institutions are subject to $10,000 in FDA-issued fines per late day, the FDA has not yet collected any such penalties from non-compliant sponsors, totaling over **$20 billion** today.

In May 2021, UAEM launched a new report examining the reporting rates amongst the top 40 research universities in the U.S. This serves as a follow-up from a 2019 report examining reporting rates at these universities. These institutions account for nearly one third of all clinical trials and billions of dollars in public funding for biomedical research in the U.S. UAEM's report shows an overall improvement in university reporting, where the number of 100% compliant institutions increased from 13 in 2019 to 17 in 2021. There was also a decrease in the percentage of unreported trials from 31% in 2019 to 7% in 2021. More importantly, 36 of the 40 institutions were at reporting levels above 80%, compared to just 16 of 40 in 2019, reflecting the advocacy of UAEM and its allies. However, institutions such as the University of Cincinnati, NYU Langone Health, and UC Denver are still amongst the least compliant, with reporting rates as low as 25%. There continue to be many other universities and pharmaceutical trial sponsors

beyond these 40 institutions that must also achieve 100% compliance to ensure complete transparency. However, this report proves that there are critical steps that research institutions can take to achieve this goal and prioritize transparency. Some ways include hiring full-time staff to input trial data, sending periodic reminders to researchers, and investing greater time and money to develop standardized protocols for clinical trial reporting at each university.

The World Health Organization (WHO) advocates for **reporting results from *all* clinical trials**, and UAEM maintains that this should be our ultimate objective as we work to render clinical research more transparent, effective, and impactful. UAEM calls on universities and research institutions to fulfill their ethical and legal obligations to report clinical trial data. The WHO and other international, national, and local public health agencies must also work to foster greater discussion on the importance of clinical trials transparency and promote the creation of stronger policies that not only improve reporting rates but also increase enforcement and regulation at research institutions across the globe.

Please refer to UAEM's 2021 Transparency Report for more information.