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The EU Biotech Act must safeguard ethical standards for clinical trials

The Standing Committee of European Doctors (CPME) and the World Medical Association (WMA) today jointly organise a policy briefing discussing solutions to maintain ethical safeguards in clinical trials, as the EU looks to increase its global competitiveness in life sciences and biotechnology.

Through measures such as the recently proposed Biotech Act, the EU is currently assessing how to develop the ecosystem for multi-country and multi-centre clinical trials, and to enable better health data sharing for research and innovation.

Against this background, risks of oversimplification and potential for unchecked deregulation increase, as well as concerns over patient safety, dilution of ethical oversight, data privacy, unequal access to medicinal products and ethical fairness.

The WMA's [Declaration of Helsinki](#), first adopted in 1964 and last revised in 2024, is the internationally accepted standard for designing, conducting, recording and reporting clinical trials. The Declaration underlines, among other, that rights, interests, and well-being of research participants must always take precedence over scientific and societal interests.

Dr Christofer Lindholm, Chair of the WMA Medical Ethics Committee, said "As the European Union seeks to strengthen its global competitiveness in clinical research, it is vital that ethical safeguards are not weakened in the name of innovation.

"The Declaration of Helsinki provides the clear ethical framework needed to ensure that clinical trials conducted in Europe continue to respect human dignity, informed consent, independent ethical oversight, and the protection of vulnerable populations. Competitiveness and bioethics are not opposing goals. Ethical rigor is essential to scientific credibility, public trust, and sustainable medical progress."

CPME President Dr Ole Johan Bakke added, "We want policy-makers and stakeholders to hear doctors' appeal that medical ethics, scientific progress and patients' rights are not competing priorities, but inseparable."

Note to editors

*The **Standing Committee of European Doctors** ([CPME](#)) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.*

*The **World Medical Association** ([WMA](#)) is the global federation of National Medical Associations representing the millions of physicians worldwide. Acting on behalf of patients and physicians, the WMA endeavors to achieve the highest possible standards of medical care, ethics, education and health-related human rights for all people.*