Biotech Act Proposal

Joint Position Statement – 11 May 2026

European Network of Research Ethics Committees (EUREC) - Standing Committee of European Doctors (CPME) – Council for International Organizations of Medical Sciences (CIOMS)

General remarks

Facing a declining share in global clinical trials, the European Union is seeking to strengthen its competitiveness and enhance support for biomedical innovation. The European Commission's (EC) ambitious Biotech Act proposal, published on 16 December 2025 and currently under consideration by the European Parliament and the Council, is central to this ambition. It proposes wide-sweeping changes aimed at creating a more streamlined and efficient clinical trials ecosystem across European Member States.

Strengthening clinical research is not only a matter of competitiveness and fostering collaboration but also a public health priority. In the aftermath of the COVID-19 pandemic, the World Health Organization emphasised the importance of robust and efficient clinical research systems through World Health Assembly Resolution WHA75.8 on strengthening clinical trials to provide high-quality evidence and improve research quality and coordination.[1] It is welcome that the changes proposed in the Biotech Act are aligned with those set out in WHA75.8.

Against this background, the European Network of Research Ethics Committees (EUREC), the Standing Committee of European Doctors (CPME) and the Council for International Organizations of Medical Sciences (CIOMS) welcome the EC's Biotech Act proposal as a timely initiative to strengthen the European clinical research environment, accelerate authorisation timelines, streamline and simplify procedures, enhance Europe's preparedness for future public health emergencies, and support global competitiveness. Importantly, the Biotech Act reaffirms the central role of high ethical standards in biomedical research.

1. We particularly welcome new Art. 83(2) of Regulation (EU) No 536/2014 on clinical trials (Clinical Trials Regulation, CTR) highlighting the necessity for the Competent Authorities and RECs to be adequately resourced. This is especially important with the added complexity of coordinated assessments of combined studies (Art. 14c CTR). Research Ethics Committees (RECs) and their secretariats/personnel must have the necessary resources to fulfil their duties and meet the requirements under the Biotech Act.

[1] https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75_R8-en.pdf

2. At the same time, we commend new Art. 83a CTR for strengthening coordination between Competent Authorities and RECs at the national level, and potentially at the EU level, which could improve consistency and effectiveness in the clinical trial evaluation process.
3. The reinforced role of RECs in the governance of clinical trials, including their participation in coordination structures such as the Clinical Trials Coordination and Advisory Group (CTAG) (new Art. 85 para. 2 CTR), is particularly welcome, as it strengthens the integration of ethical oversight.
4. The proposal reflects core principles of the World Medical Association's Declaration of Helsinki (DoH), particularly the emphasis on responsible inclusion and the protection of research participants, including vulnerable populations (recital 139).
5. The proposal is also broadly consistent with the principles reflected in the recent revision of the International Council for Harmonisation Good Clinical Practice Guideline (ICH-GCP(R3)), which promote flexibility, risk-proportionate approaches, and high standards in clinical trial conduct.

    5.a The introduction of regulatory sandboxes is potentially a positive development, to the extent that the principles of research ethics are respected, as it enables more flexible and innovation-friendly approaches to clinical trial regulation. This aligns closely with the principles of ICH-GCP(R3), which move away from one-size-fits-all requirements towards risk-proportionate and adaptive regulation. Promoting the implementation of ICH-GCP(R3) within the EU could further support more efficient and inclusive clinical research while encouraging critical thinking and flexibility, qualities that are particularly responsive to the needs of academic research.

    5.b The systematic implementation of ICH-GCP(R3) is also a useful step to improve EU preparedness for public health emergencies, aligned with the resolution WHA75.8 and the proposed Guidance on the Conduct of Clinical Trials During Public Health Emergencies from Accelerating Clinical Trials in the European Union (ACT EU), which is currently under consultation.

Suggestions for consideration

A- Research ethics (DoH)

Although the Biotech Act proposal and the CTR revision have clear references to the Declaration of Helsinki (2024), several elements deserve to be covered more explicitly:

A-1 Responsible inclusion: the rewriting of Art. 10 CTR is very positive, but only Art. 31 CTR (minors) and Art. 32 CTR (incompetent adults) have been properly amended. To avoid confusion and in accordance with the principle of responsible inclusion, a rephrasing of the new Art. 33 para. 2 (pregnant and lactating women) should be considered. Such revision should cover both circumstances where women are pregnant or lactating at the time of their inclusion or become pregnant or begin lactating during their participation:

> **Proposed new Art. 33 para. 2 CTR:** The responsible inclusion of pregnant or lactating women should be considered systematically, and their exclusion must be justified.

This provision must be read in the light of the first paragraph of Art. 33 CTR, which ensures the protection of the woman, the foetus, and the child. The intention is therefore not to decrease their protection, but to avoid overprotection resulting in systematic exclusion from research, which is ultimately detrimental to the health interests of pregnant and lactating women due to the lack of evidence-based treatments. This should encourage and facilitate more trials involving pregnant or lactating women, especially for new indications of existing medicinal products for which real-world data exist on their safety for pregnant and lactating women.

A-2 Patient and public involvement and engagement (PPIE): As required in the DoH (Art. 6 para 3) and ICH-GCP(R3), the meaningful engagement of potential participants and their communities is essential both in terms of respect and methodology. Having patients and their communities involved at an early stage in the design, development and conduct of clinical trials contributes to more efficient and inclusive clinical research and avoids research waste. Without dedicated resources and capacity-building measures, PPIE risks remaining a formal requirement rather than a meaningful contribution to clinical research. PPIE and its funding should therefore be explicitly mentioned in the Biotech Act proposal and at a minimum in the CTR.

> **Proposed new Recital 139bis Biotech Act:** To ensure that clinical trials are responsive to the health needs and priorities of the concerned communities and populations and conducted in respect of their interests, their meaningful engagement before, during, and following clinical trials is essential. Early engagement of potential and enrolled participants and their communities in the design and conduct of clinical trials improves recruitment, inclusiveness and reduces waste in research. The importance of Patient and Public Involvement and Engagement (PPIE) is recognized as a fundamental principle in research ethics including the World Medical Association's Declaration of Helsinki and the Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Health-related Research Involving Humans (2016).
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> **Proposed new Art. 28 para. 1bis CTR:** Meaningful engagement with potential and enrolled participants and their communities shall be considered systematically. Member States shall build capacity to ensure effective patient and public involvement and engagement in the design and conduct of clinical trials.

A-3 Data Protection: The proposed revision of Art. 93 CTR raises serious concerns. Paragraphs 6 and 7 introduce a derogation to Article 9(4) of Regulation (EU) 2016/679 that potentially jeopardises public trust, especially when read in light of Recital 152: “Member States should not be able to maintain or introduce under Article 9(4) of Regulation (EU) 2016/679 further conditions, including limitations and specific provisions such as requesting the consent of natural persons in the sense of that Regulation”.

The proposed provisions significantly broaden the scope for the further processing of personal data for additional clinical trials and scientific research purposes, while limiting the ability of Member States to maintain or introduce additional safeguards under Article 9(4) of Regulation (EU) 2016/679. At the same time, the current formulation risks creating an imbalance whereby sponsors may benefit from broad secondary use of data without corresponding guarantees of transparency or wider scientific accessibility.

These provisions should be comprehensively redrafted to ensure clearer safeguards, greater transparency, and an appropriate balance between research efficiency and the protection of personal data. The EU must avoid eroding public trust.

A-4 Terminology: We strongly suggest moving from the outdated use of "subjects" to "research participants" in accordance with the Declaration of Helsinki (2024) and the CIOMS International Ethical Guidelines for Health-related Research Involving Humans (2016) as well as the French, German or Spanish versions of the CTR. Such an important change, expressing respect for research participants, including healthy volunteers, should be implemented in the Biotech Act proposal as well as all relevant regulations.

B- Shortening timelines and regulatory simplification

B-1 Shorter clinical trial authorisation timelines may attract commercial sponsors but could unintentionally disadvantage non-commercial / academic researchers and Small and Medium-sized Enterprises (SMEs). Experience from previous regulatory reforms (e.g., the Clinical Trials Directive) suggests that insufficient attention to implementation challenges can negatively affect academic research. The lack of resources in academic research and the fact that academic researchers are frequently engaged in routine clinical duties mean they are often unable to respond to the Competent Authorities and RECs within the required timeframe. The difficulty for academic institutions to meet the deadlines is also accentuated by the fact that they are often the settings in which patient involvement is most innovative and meaningful, requiring more time to ensure that patients and communities have genuine opportunities to share their priorities and values.

B-2 Any acceleration of procedures should therefore include appropriate flexibility mechanisms for academic sponsors and SMEs, whilst also ensuring the robustness of clinical trial conduct. This should be better acknowledged in the CTR by providing them with more time to fulfil their requirements, unless more resources could be allocated to them.

B-3 Whilst we commend shorter timelines for conducting and concluding clinical trials, efforts to shorten procedural timelines should not be pursued as an objective in themselves, but rather as a result of strengthening the overall clinical trials ecosystem, including adequate resources, coordination, and governance, with the goal of commencing clinical trials faster, in the interest of the research participant and of driving innovative healthcare and treatment.

C- Resources and capacity building

C-1 The recent EU Guidance on the Conduct of Clinical Trials During Public Health Emergencies (PHE), developed under the ACT EU represents an important step towards strengthening Europe's preparedness and addressing key shortcomings identified during the COVID-19 pandemic. However, effective implementation of this guidance and PHE measures proposed under the Biotech Act will depend on the capacity of national systems, in particular RECs. Strengthening REC networks across the EU, together with adequate and sustained funding, will therefore be essential to ensure timely and robust ethical review in emergency situations, and to implement accelerated (authorisation) procedures as envisaged under the Biotech Act (Art. 14b).

C-2 Beyond the reinforced coordination between Competent Authorities and RECs as promoted by new Art. 83a CTR, we must stress the necessity to support and facilitate the networking of the RECs themselves, especially at the EU level. This is an essential condition for the harmonious implementation of the Biotech Act proposal.

C-3 The Biotech Act proposal introduces several measures intended to support clinical research, including the recognition of Health Biotechnology Strategic Projects (Art. 3), Biotechnology Development Accelerators (Art. 5), Centres of Excellence for Advanced Therapies (Art. 6), and additional administrative support mechanisms (Art. 13). However, the proposal remains unclear about the practical implications of these initiatives and the concrete benefits they would bring to researchers, sponsors, and the broader EU population. If such recognition were accompanied by additional resources — for example through prioritisation within EC research programmes or increased support from Member States — these initiatives could have a meaningful impact. However, without dedicated funding and appropriate governance mechanisms, in accordance with the CIOMS International Guidelines on Good Governance Practice for Research Institutions (2023), their practical effect remains unclear. The countries in Europe which are not experiencing a decrease in the number of clinical trials have demonstrated the significant return on investment in their efforts to support and strengthen research infrastructures. All Member States need to actively support the implementation of the Biotech Act proposal as it is in their direct interests and those of the population.

Annex: Proposed Amendments

Proposed new Recital 139bis Biotech Act:

To ensure that clinical trials are responsive to the health needs and priorities of the concerned communities and populations and conducted in respect of their interests, their meaningful engagement before, during, and following clinical trials is essential. Early engagement of potential and enrolled participants and their communities in the design and conduct of clinical trials improves recruitment, inclusiveness and reduces waste in research. The importance of PPIE is recognized as a fundamental principle in research ethics including the World Medical Association's Declaration of Helsinki and the Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Health-related Research Involving Humans (2016).

Proposed new Art. 28 para. 1bis CTR:

Meaningful engagement with potential and enrolled participants and their communities shall be considered systematically. Member States shall build capacity to ensure effective patient and public involvement and engagement in the design and conduct of clinical trials.

Proposed new Art. 33 para. 2 CTR:

The responsible inclusion of pregnant or lactating women should be considered systematically, and their exclusion must be justified.

Terminology

Replace "**subjects**" by "**research participants**" in the Biotech Act proposal as well as all relevant regulations, in particular the CTR.