Biomedical Alliance in Europe

Strengthening Academic Clinical Research for a Competitive European Biotechnology Ecosystem

BioMed Alliance response to the European Commission consultation on the European Biotech Act proposal (2025/0406/COD)

Introduction

The BioMed Alliance welcomes the European Commission's initiative to develop a European Biotech Act as an important opportunity to strengthen Europe's biotechnology ecosystem, enhance its global competitiveness and accelerate the translation of scientific innovation into solutions that benefit society. To achieve these objectives, the Act should support the full innovation pathway, from research and development to evidence generation and the uptake of innovative solutions, including in the healthcare sector.

Academic clinical research is a key contributor to biomedical innovation, generating independent evidence, addressing unmet medical needs and advancing scientific and clinical questions beyond commercial priorities. However, the regulatory and financial barriers that limit academic sponsors' ability to develop health solutions and contribute to Europe's innovation capacity, are insufficiently addressed in the Biotech Act. BioMed Alliance, representing 34 European Medical and Research Societies, calls for a Biotech Act that recognises the strategic role of academic clinical research and supports it through proportionate regulation, sustainable funding and strengthened research capacity.

Summary of our recommendations:

- **Recognise academic and non-commercial research organisations as strategic contributors to Europe's biotechnology ecosystem**
- **Include concrete mechanisms to support low-intervention clinical trials (LICTs) and simplify regulatory processes for LICTs.**
- **Establish dedicated EU support mechanisms for academic biotechnology development, including late-stage clinical research and pivotal clinical trials.**
- **Harmonising and streamlining Informed Consent Forms (ICFs).**
- **Strengthen the EU Health Biotechnology Support Network as a resource for academic developers.**
- **Introduce public return requirements for publicly funded biotechnology innovation.**

Strategic role of academic clinical research

Non-commercial or academic clinical trials are a strategic component of Europe's biotechnology ecosystem. Approximately 20% of clinical trial applications submitted in the European Union originate from non-commercial sponsors, including universities, academic medical centres and research

institutions[1]. These studies address scientific and clinical questions that are generally beyond the scope of commercial development but are essential for improving patient care and healthcare systems[2].

Academic research generates independent evidence on comparative effectiveness, treatment optimisation, dose and duration, sequencing and combination of therapies, long-term safety and effectiveness, identification of patients most likely to benefit from treatment, and the evaluation of interventions in underserved patient populations (1-3). Such evidence is fundamental to the development of clinical guidelines, health technology assessment, reimbursement decisions and evidence-based healthcare.

Academic investigators are also critical drivers of innovation in rare diseases, paediatric medicine and drug repurposing, where commercial incentives alone are frequently not sufficient. A recent analysis showed that 75% of the developments of repurposed orphan drugs authorised during the 2016-2020 period were started in academia[3] . This highlights the indispensable role of academic clinical research in expanding therapeutic options, promoting biotechnology innovation while helping to address important unmet medical needs.

Beyond individual studies, academic clinical research also strengthens Europe's scientific capacity by fostering multinational collaboration, developing research infrastructures and training future clinical investigators. Nevertheless, this sector continues to experience several challenges.

Challenges limiting academic clinical research

The scientific and operational environment in which academic clinical trials are conducted has changed substantially over the past decade. The implementation of the Clinical Trials Regulation (EU) No 536/2014[4], the Clinical Trials Information System (CTIS)[5] and the ACT EU initiative[6] represents an important step towards a more harmonised and efficient European clinical research framework. These initiatives have improved the coordination of multinational clinical trials and strengthened regulatory collaboration across Member States. However, experience from academic sponsors demonstrates that regulatory harmonisation alone is insufficient to address the structural barriers affecting academic clinical research.

Regulatory

A key challenge is that the current regulatory framework does not always sufficiently account for the specific characteristics and risk profiles of academic and public-benefit clinical research. In particular, low- and minimal-intervention clinical trials may face requirements designed for higher-risk trials, resulting in disproportionate administrative and documentation burdens for non-commercial sponsors. This is particularly relevant for academic clinical research, which plays an important role in addressing questions related to treatment optimisation and improving patient care. A more genuinely risk-proportionate approach, including simplified requirements for low- and minimal-intervention clinical trials, is therefore needed to reduce unnecessary administrative burden and provide greater legal certainty for academic sponsors.

Further challenges remain regarding the harmonisation of regulatory procedures across Member States. Differences in informed consent requirements, as well as variations in the coordination between ethics

[1] Entry into application of the Clinical Trials Regulation - Public Health
[2] Academic clinical cancer trials to improve patient outcomes - The Lancet Oncology
[3] Frontiers | Drug Repurposing for Rare Diseases: A Role for Academia
[4] Clinical Trials Regulation | European Medicines Agency (EMA)
[5] Clinical Trials Information System | European Medicines Agency (EMA)
[6] Accelerating clinical trials in the EU

committees and competent authorities, continue to contribute to fragmentation and create barriers for multinational academic clinical trials. These challenges can delay the initiation and conduct of academic studies and limit the ability of researchers to undertake collaborative research across Europe.

In addition, academic developers often lack the regulatory expertise and capacity needed to identify, anticipate and navigate appropriate regulatory pathways. Without adequate regulatory support, promising academic innovations may face delays in development or difficulties progressing through the appropriate regulatory pathways. Dedicated regulatory assistance, including through the EU Health Biotechnology Support Network and the Regulatory Status Repository, should therefore support academic developers in identifying and using appropriate regulatory procedures and support mechanisms. Such support should not be limited to Strategic Projects, recognising that academic innovation frequently addresses unmet medical needs where commercial incentives may be limited.

Financial

Beyond regulatory barriers, academic clinical research continues to face persistent challenges in securing sustainable funding, particularly for advanced therapies and pivotal clinical trials. Academic developers frequently generate promising innovations but face a critical funding gap when moving from early research to clinical development. The transition towards clinical validation requires substantial resources that are often beyond the capacity of academic institutions. This challenge is particularly pronounced for innovations addressing unmet medical needs or patient populations where commercial incentives are frequently insufficient.

The current Biotech Act proposal provides limited incentives and support mechanisms specifically tailored to academic and other non-commercial research. In particular, the eligibility criteria for health biotechnology strategic projects (Article 3) are unlikely to accommodate many academic institutions. This is because the proposed framework appears primarily oriented towards entities with established development capacity, investment readiness and commercialisation pathways, which many academic institutions do not possess despite their ability to generate impactful innovations. While strengthening the EU's competitiveness in biotechnology is an important objective, the current proposal does not adequately support or incentivise academic and public-benefit research as a key contributor to innovation and equitable patient access across the European Union.

Furthermore, EU funding has predominantly targeted high-risk, high-reward biotechnology innovation, which is often subsequently licensed to companies, while academic clinical research continues to face difficulties securing resources for late-stage development. Greater financial and structural support is therefore needed for non-commercial initiatives with the potential to benefit patients across all Member States. Public investment should also be accompanied by mechanisms that ensure transparency, affordability, equitable patient access and reinvestment in public health, supported by strong monitoring and reporting requirements.

Recommendations to strengthen Europe's academic clinical research ecosystem

The BioMed Alliance welcomes several measures proposed in the European Biotech Act, including the removal of barriers to paediatric clinical trials (Art. 32), a strengthened role for the Reporting Member State (RMS), accelerated procedures for public health emergencies, regulatory sandboxes, and provisions supporting combined studies and the use of artificial intelligence in clinical trials. Together, these

measures have the potential to simplify and accelerate clinical research in Europe while maintaining high standards of patient safety and scientific quality.
To further strengthen Europe's biotechnology ecosystem and maximise the contribution of academic clinical research, the BioMed Alliance recommends that the European Biotech Act should:

- **Recognise academic and non-commercial research organisations as strategic contributors to Europe's biotechnology ecosystem.** The eligibility criteria for health biotechnology strategic projects (Article 3) should be adapted to ensure that academic institutions and public-benefit organisations can access support where their innovations address unmet medical needs and have significant potential for patient benefit.
- **Include concrete mechanisms to support low-intervention clinical trials (LICTs) and simplify regulatory processes for LICTs.** These trials play an important role in conducting treatment optimisation trials, de-escalation studies, as well as comparisons of treatments that are recommended by clinical guidelines or widely used in clinical practice and have an established safety profile. Article 2(2) should clarify the scope of LICTs, which should be included in the exception under Article 6(2a) to ensure risk-proportionate requirements. Applying a proportionate ethical review to de-escalation studies and trials evaluating established clinical practices would reduce administrative burden and allow national competent authorities to focus resources on higher-risk, more uncertain trials. More detailed information and concrete suggestions to improve LICTs can be found in the European Hematology Association's publication on the Biotech Act[7].
- **Establish dedicated EU support mechanisms for academic biotechnology development, including late-stage clinical research and pivotal clinical trials.** Funding instruments should address the specific challenges faced by non-commercial developers in translating promising innovations into clinical applications, particularly for advanced therapies and areas with limited commercial incentives.
- **Harmonising and streamlining Informed Consent Forms (ICFs).** Although Part I of the assessment report is submitted jointly, Part II requires separate national versions of the same documents, as ethics committees assess them under their own legal and ethical requirements, including local-language ICFs. This leads to country-specific adaptations and a lack of harmonisation. The current approach increases complexity and makes it harder to develop clear, patient-friendly ICFs that support informed decision-making. We recommend including standardised EU-wide informed consent elements, such as trial procedures, screening tests, potential risks, side effects, and expected benefits. In addition to this, include country-specific information, such as local treatment options, data protection requirements, and rules on biological sample storage. This would improve harmonisation, reduce administrative burden, and support clearer communication with patients.
- **Strengthen the EU Health Biotechnology Support Network as a resource for academic developers.** Regulatory assistance under Article 34 should be available to academic and public-benefit innovators regardless of whether a project is designated as a strategic biotechnology project. The Network should support developers in identifying appropriate regulatory pathways, accessing regulatory support mechanisms and navigating requirements for clinical development.
- **Introduce public return requirements for publicly funded biotechnology innovation.** EU funding mechanisms should include transparency, monitoring and reporting requirements, as well as measures to promote affordability, equitable patient access and reinvestment in public

[7] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14627-Biotech-Act/F33530942_en

health. Public investment should not only contribute to scientific innovation, but also to sustainable healthcare delivery across all Member States.

Conclusion

Academic clinical research is a fundamental pillar of Europe's biotechnology ecosystem, complementing industrial innovation by generating independent evidence, addressing unmet medical needs and supporting evidence-based healthcare. However, regulatory complexity, insufficient funding and uneven institutional capacity continue to limit its contribution.

The European Biotech Act provides an opportunity to create a more balanced ecosystem in which both commercial and academic innovation pathways are supported. By strengthening regulatory proportionality, sustainable investment and institutional capacity, Europe can improve its ability to translate scientific discoveries into clinical advances and ensure that biotechnology innovation delivers meaningful benefits for patients across all Member States.