

## EORTC's position on the Biotech Act

### Overview

The European Organisation for Research and Treatment of Cancer (EORTC) welcomes the Biotech Act as an initiative to support clinical research by improving the European legal framework.

The Act's preamble explicitly outlines a commitment to supporting clinical trial sponsors, and particularly non-commercial sponsors that conduct the majority of minimal- and low-intervention clinical trials in the Union. The stated goal is to provide these sponsors with **simplified, risk-proportionate regulatory requirements** and a reduced administrative burden, while ensuring that patient safety and well-being remain protected.

However, a closer look at the proposed amendments reveals a significant disconnect. Despite these objectives, the current text lacks concrete mechanisms to support **low-intervention clinical trials** (LICTs). Instead, we find a **regulatory void**; the amendments rely on vague phrasing, suggesting only that requirements "shall be simplified" or "may be adapted," without providing the necessary detail to achieve these goals.

Non-commercial sponsors play a pivotal role in conducting **treatment optimisation trials**, as recognised in Recital (29) and mandated under Articles 12 and 20 of the General Pharmaceutical Regulation<sup>1</sup>. These trials seek to refine the use of therapeutic interventions, often by addressing the over-utilisation of treatments. In such cases, these studies expose patients to lower doses or shorter treatment durations than what is supported by existing data or the registered label. Consequently, such trials can be categorised as LICTs.

To better support this research, these trials, much like minimal-intervention clinical trials, should be eligible for a **simplified regulatory pathway**. This would also align the Act with practices already established in other jurisdictions.

To tackle this, **we are calling for a revisited definition and a simple regulatory process for LICTs** (in attached Annex). **Instead of fulfilling all regulatory requirements that are designed for standard trials, these trials should only need Ethics Committee approval (as is the case for the proposed minimal-intervention category). This is a reasonable remedy that reflects the actual minimal risk of the study, leaving no room for confusion or delay.**

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<sup>1</sup> Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing the rules governing the European Medicines Agency



## ANNEX

### Technical Amendments

We welcome the addition of the new category of “minimal-intervention clinical trials”, in addition to the existing category of low-intervention clinical trials under the Clinical Trials Regulation (CTR). This category applies to investigational medicinal products that are already authorised, used in accordance with the terms of the marketing authorisation, and pose minimal risk to patient safety.

We advocate for a streamlined pathway under Article 6 of the CTR to ensure that both LICTs and MICTs are governed by a process proportionate to their actual risks, centred solely on Ethics Committee approval. This unified regulatory route acknowledges that when the safety profile of an intervention is already well-established, the ethical oversight of patient welfare is the primary standard for trial commencement.

To transform the Biotech Act into a truly game-changing regulation, we propose the following strategic refinements:

- 1) The definition of low-intervention clinical trials in the Act should draw upon pragmatic approaches existing in other jurisdictions to capture context-based established clinical practice.
- 2) The regulatory trajectory for LICTs should be harmonised with the pathway established for MICTs, as both categories impose only minimal additional risk to the safety of the subjects. This would ensure legal certainty and leave no room for diverging interpretations among Member States.

To achieve these objectives, we propose specific amendments to Article 58 of the Biotech Act, which modifies Regulation (EU) No 536/2014 (CTR). Specifically, our proposal advocates for a refined definition of LICTs under the amended Article 2(3) CTR to more accurately capture context-based established clinical practice.

The current regulatory void for LICTs under the Act fails to provide the procedural certainty required for low-risk clinical research. By establishing a shared regulatory pathway for both LICTs and MICTs under Article 6(2a) CTR centred on Ethics Committee oversight, the framework effectively eliminates administrative ambiguity, preventing unnecessary delays in trial initiation.

This unified approach would synchronise the Biotech Act with the pragmatic, risk-based notification schemes adopted in other jurisdictions (such as the notification scheme for Notifiable Trials in the UK<sup>2</sup>), ensuring that the EU’s regulatory framework reflects the reality of modern clinical research without compromising patient safety.

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<sup>2</sup> Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2024



## Legal provisions to be amended within the Biotech Act

(our suggestions are in red)

**Article 58: Regulation (EU) 536/2014 (CTR) is amended as follows:**

### **PART I: Definition of LICTs**

- Article 2 is amended as follows:

**(a)** point (3) is replaced by the following:

'(3) 'Low-intervention clinical trial' means a clinical trial which fulfils all of the following conditions:

(a) the investigational medicinal products, excluding placebos, are **authorised**; or they have **been approved in other clinical trials in the EU whereby—**

**1. the product was investigated at:**

**(i) the same or higher dose,**

**(ii) the same or higher frequency, and**

**(iii) the same or longer duration;**

**2. the same manufacturing process was utilised for the product; and**

**3. the approved trial:**

**(i) utilised the same route of administration for the product, and**

**(ii) investigated the product for the same disease.**

(b) according to the protocol of the clinical trial, the use of the investigational medicinal product is ~~evidence-based and supported by published scientific evidence on the safety and efficacy of those investigational medicinal products concerned~~ **supported by internationally established clinical practice<sup>3</sup>**; and

(c) the additional diagnostic or monitoring procedures do not pose more **than minimal additional risk** or burden to the safety of the subjects compared to normal clinical practice in any Member State concerned;'

**(b)** the following point (3a) is inserted:

'(3a) 'Minimal-intervention clinical trial' means a clinical trial which fulfils all of the following conditions:

(a) the investigational medicinal products are authorised;

(b) according to the protocol of the clinical trial, the investigational medicinal products are used in accordance with the terms of marketing authorisation;

(c) and the additional diagnostic or monitoring procedures do not pose more than minimal additional risk or burden to the safety of the subjects compared to normal clinical practice in any Member State concerned';

### **PART II: Regulatory Pathway Implications**

- Preamble (138) is amended as follows: *Clinical trials that meet the criteria for minimal-intervention and low-intervention clinical trials should only require an ethical review before the clinical trial can begin. An enhanced application of a risk-proportionate approach will contribute to fostering a regulatory framework that is conducive to research and innovation. Sponsors, particularly non-commercial ones who conduct the majority of minimal-intervention*

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<sup>3</sup> This could include clinical guidelines or peer-reviewed literature



*and low-intervention clinical trials in the Union, will greatly benefit from simplified and risk-proportionate regulatory requirements through a reduced administrative burden, while not compromising subjects' safety, well-being, and rights. A reinforced application of a risk-proportionate regulatory framework further allows Member States to concentrate on their assessment on clinical trials associated with greater risk to the subjects.*

- Article 6 is amended as follows:

#### Article 6

##### Assessment report – Aspects covered by Part I of the assessment report

1. The reporting Member State shall assess the application relying on the information and the documents listed in Part I of Annex I, with regard to the following aspects:

...

2a. Notwithstanding paragraph 2, where the clinical trial is a minimal-intervention **or low-intervention** clinical trial, the assessment of the reporting Member State shall be limited to an ethical review by its ethics committee of the aspects referred to points (a) and (d) of paragraph 1.

#### About EORTC

The European Organisation for Research and Treatment of Cancer (EORTC) is a large independent cancer clinical research organisation. The EORTC has delivered investigator driven, practice changing clinical trials since 1962. Its mission is to improve survival and quality of life of cancer patients. The EORTC is a not-for-profit independent organisation performing multidisciplinary clinical research activities across tumour types. EORTC's activities involve on a voluntary basis more than 2800 doctors and scientists from some 900 university hospitals in 48 countries. EORTC clinical trials are involving several thousands of patients on a yearly basis. The scientific activities of EORTC are strictly peer-reviewed and subject to quality assurance/ quality control programs. The EORTC operates on an independent basis, and in this capacity can work in partnership with the pharmaceutical industry. EORTC has contributed to several success stories in terms of the development of new anti-cancer drugs including registrations by the FDA and the EMA. More information



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