Towards a More Proportionate EU Framework for Low-Intervention Clinical Trials:

Lessons from the United Kingdom and Switzerland

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Background

- Treatment optimisation studies examine lower doses, shorter duration, interruptions or alternative schedules of established therapies, and address specific patient populations such as older or frail adults.
- These trials may reduce toxicity, improve quality of life, and support more sustainable care.
- Evaluating these potential benefits involves testing new strategies with established medicines. Product and strategy risks warrant distinct safeguards, but strategy risk should not, on its own, trigger requirements designed for unauthorised products.

Research Question: How can the EU regulate low-risk clinical trials more proportionally to their inherent medical risk to better support research that addresses public health needs by drawing on the UK and Swiss frameworks?

Materials and Methods

Comparative Legal and Policy Analysis (EU • UK • CH) → Identify eligibility criteria for low-risk classification → Examine regulatory implications following classification → Case Study: EORTC 2238 "DE-ESCALATE" prostate cancer trial → Highlight divergences and propose recommendations

Results

Comparison of Regulatory Approaches

Criteria for low-risk	EU Biotech. Act / CTR	UK Medicines for Human Use (Clinical Trials) Regulations 2025	CH Clinical Trials Ordinance (ClinO, SR 810.305)
Basis for recognising accepted clinical use	Evidence-based use	Established clinical practice	Recognised standard use
Review pathway	Full CTIS authorisation; Part I and Part II	Notification-based pathway	Ethics Committee approval only
Impact	Limited practical impact	Proportionate requirements	Exempt from Swissmedic authorisation

DE-ESCALATE: Divergence in practice

Clinical question:
In patients with metastatic hormone-sensitive prostate cancer who achieve a deep PSA response, can intermittent maximal androgen blockade preserve overall survival compared with continuous treatment?

EU EXPERIENCE

LICT category refused

~9-month delay (+ 72 RFIs)

Activation costs >6× higher

Earlier evidence did not validate intermittent use of current agents. Application withdrawn and resubmitted.

SWISS EXPERIENCE

Category A

Ethics Committee approval only

No Swissmedic authorisation. Established medicines and limited additional risk.

Discussion / Recommendations

1. **CLARIFY ELIGIBILITY CRITERIA**
   Recognise established clinical practice and define acceptable evidence, including guidelines, registry data, real-world evidence, and peer-reviewed literature.
2. **SIMPLIFY THE REGULATORY PATHWAY**
   Link low-risk status to accelerated notification in CTIS and, where appropriate, an Ethics Committee-centred route.

The proposed Biotech Act could offer a timely opportunity to refine the EU's LICT definition and ensure that qualifying studies, such as non-commercial treatment optimisation studies, can benefit from simplified review pathways, aligning regulatory scrutiny with their actual risk and public health impact.