European University Hospital Alliance

July 13th, 2026

European University Hospital Alliance
Warmoesberg 26
1000 Brussels, Belgium

Dear Sir or Madam,

The European University Hospitals Alliance (EUHA), representing leading university hospitals across Europe, welcomes the European Commission's efforts to refine the regulatory framework under the In Vitro Diagnostic Regulation (IVDR) and the Medical Device Regulation (MDR).

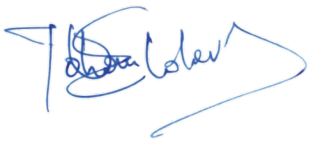
EUHA member hospitals are firmly committed to quality, patient safety and regulatory compliance. Our institutions operate under robust, externally audited quality management systems and national oversight. Innovation and care delivery span multiple hospital departments. We have in a previous letter already set out EUHA's key positions on the proposed amendments to the MDR and IVDR. The MDR has significantly strengthened the European regulatory framework for medical devices and has contributed to a high level of patient safety and public confidence. However, the current framework remains primarily designed around clinical investigations conducted by manufacturers for the purpose of conformity assessment/CE marking.

University hospitals, academic institutions, public research organisations and non-profit healthcare providers conduct many clinical investigations that pursue fundamentally different objectives. These studies are often undertaken in the public interest and aim to improve healthcare delivery, evaluate comparative effectiveness, validate artificial intelligence applications, assess hospital-developed technologies, generate real-world evidence, optimise care pathways, and support health system innovation.

Article 82 MDR provides the legal basis for such investigations. However, the current implementation of Article 82 has resulted in significant fragmentation across Member States. National differences in procedures, documentation requirements, and approval pathways create unnecessary administrative burden, increase costs, delay study initiation, and discourage multinational academic research. This also results for patients in unequal access to these studies.

Europe requires a harmonised framework that preserves the highest standards of patient safety while facilitating investigator-initiated research and innovation and equal access for patients. In this letter EUHA sets out its reflections and proposals for an amended art 82 in further detail, with the intention to support clinical investigations in non-profit institutions while ensuring proportionality, patient safety and legal certainty for health institutions.

Yours sincerely,



On behalf of the European University Hospital Alliance

Prof Dr Johan Van Eldere MD, PhD, MHM

Secretary-General | European University Hospital Alliance

European University Hospital Alliance

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Proposal for the revision of Article 82 MDR: Towards a Harmonised European Framework for Investigator-initiated Clinical Investigations

Background

The Medical Device Regulation (MDR) has significantly strengthened the European regulatory framework for medical devices and has contributed to a high level of patient safety and public confidence. However, the current framework remains primarily designed around clinical investigations conducted by manufacturers for the purpose of conformity assessment/CE marking.

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Guiding Principles

A revised Article 82 should be based on five core principles:

- **Patient safety and participant protection must remain paramount.**
- **A clear distinction between clinical investigations for conformity assessment and those not for conformity assessment**
- **A single harmonised framework should apply across all Member States ensuring equal patient access.**
- **Regulatory requirements should be proportionate to risk.**
- **Academic and public-interest research should be facilitated rather than discouraged.**

Distinguishing between clinical investigations for conformity assessment and clinical investigations not for conformity assessment

The MDR should explicitly recognise that not all clinical investigations pursue the same objectives.

Conformity assessment studies are typically sponsored by manufacturers and are intended to support CE marking, market access, or commercial development. These studies should continue to follow the existing MDR clinical investigation framework.

Clinical investigations not for conformity assessment are typically sponsored by university hospitals, academic institutions, public research organizations, healthcare providers, or other non-profit entities. Their primary purpose is to generate scientific, clinical, implementation, safety, performance, or health system evidence rather than to obtain market access.

A revised Article 82 should become the dedicated European framework for 'not for conformity' assessment investigations.

This distinction would not reduce standards for participant protection. All studies should continue to comply with common European requirements relating to informed consent, ethics review, risk-benefit assessment, safety monitoring, investigator qualifications, and data integrity. Rather, it would ensure that regulatory requirements are aligned with the objectives and risk profile of the investigation as is already defined in para 1 of the present article 82.

Conformity studies should follow the market-access pathway; investigations not for conformity assessment should follow the knowledge-generation pathway.

Article 82 as the framework for multinational/multicentre investigator-initiated research

Article 82 should become the primary regulatory pathway for investigator-initiated, not for conformity assessment clinical investigations conducted across multiple centres and/or multiple Member States.

This would include studies involving:

- Medical devices developed within healthcare institutions.
- Artificial intelligence and digital health solutions.
- Comparative effectiveness research.
- Real-world evidence generation.
- Quality improvement and implementation research.
- Clinical investigation of innovative technologies.
- Health system redesign initiatives.

The objective should be to facilitate collaboration between Europe's leading healthcare and research institutions while ensuring consistent regulatory oversight.

Harmonisation Across Member States

The revised Article 82 should establish a single set of harmonised European requirements applicable in all Member States.

Once an Article 82 study has been notified according to harmonised European criteria, participating Member States should recognise that authorisation without imposing additional national requirements. Member States should not be permitted to introduce supplementary procedural, documentation, or approval requirements that create barriers to multinational academic research.

This would significantly reduce duplication, administrative burden, and regulatory uncertainty while supporting the objectives of the European Research Area and the European Health Union.

Registration in EUDAMED

All Article 82 investigations should be registered in EUDAMED.

Registration would:

- Increase transparency and visibility of ongoing studies.
- Facilitate collaboration between research institutions.
- Avoid unnecessary duplication of research efforts.
- Improve regulatory oversight.
- Support the generation of real-world evidence.
- Create a potential bridge through which evidence generated in investigator-initiated studies may contribute to future conformity assessment and CE-marking activities where appropriate.

This approach would strengthen the link between academic research and innovation translation while maintaining the not for conformity assessment nature of investigator-initiated studies.

A Risk-Based Regulatory Approach

Regulatory requirements under Article 82 should be proportionate to the level of risk posed by both the device and the clinical investigation.

Factors to be considered should include:

- Device classification.
- Degree of invasiveness.
- Intended use.
- Extent of deviation from approved indications.
- Vulnerability of the study population.
- Potential impact on patient safety.

Higher-risk investigations should be subject to enhanced scrutiny and oversight, while lower-risk investigations should benefit from simplified procedures. Relevant guidelines for ethical committees should be agreed upon between all Member States.

This approach would focus regulatory resources where patient risks are greatest while avoiding unnecessary administrative burden for low-risk studies.

Simplified requirements for CE-marked devices

Clinical investigations involving CE-marked devices should remain within the scope of Article 82 when conducted as investigator-initiated multinational/multicentre studies.

Where a CE-marked device is used within its approved intended purpose and according to its instructions for use, the investigation should be presumed to present a lower level of regulatory risk and therefore qualify for a simplified assessment pathway.

Additional requirements should only be introduced when:

- The device is used outside its intended purpose.

- Significant modifications are introduced.
- New safety concerns are anticipated.
- Particularly vulnerable patient populations not included in the CE-mark are involved.

This would facilitate comparative effectiveness studies, implementation research, and real-world evidence generation while maintaining appropriate safeguards.

Hospital-Based Exemption for Single-Centre Studies

In addition to the harmonised European pathway for multinational/multicentre studies, a simplified pathway should be available for single-centre investigator-initiated studies.

Where:

- The study is conducted within a single healthcare institution.
- The institution assumes full sponsor responsibility.
- The device is used exclusively within that institution.
- Appropriate ethical review is in place.
- The investigation presents no more than low or moderate risk to participants.

Member States should be allowed to authorise such studies through a simplified local procedure. If, in subsequent follow-up studies, additional centres are included, the harmonised art 82 rules would apply.

This exemption would recognise the unique role of university hospitals as centres of innovation while ensuring full accountability for patient safety and study conduct. It would also be consistent with the principles underlying the MDR provisions for in-house devices.

Safeguarding Patient Safety

The proposed reforms are intended to improve regulatory efficiency, not to reduce participant protection.

All Article 82 investigations should continue to comply with harmonised European requirements relating to:

- Independent ethics review.
- Informed consent.
- Risk-benefit assessment.
- Safety monitoring and reporting.
- Substantial modifications
- Investigator qualifications.
- Protection of vulnerable populations.
- Data integrity and transparency.

These safeguards should apply irrespective of whether a study is for conformity assessment or not, multinational/multicentre or single centre.

Conclusion

Article 82 represents a unique opportunity to establish a coherent European framework for investigator-initiated medical device research. By creating a harmonised pathway for multinational academic studies, introducing a risk-based approach, ensuring EUDAMED registration, recognising the distinction between conformity assessment and not for conformity assessment research, and providing a proportionate hospital-based exemption for low- or moderate- risk single-centre studies, Europe can simultaneously strengthen participant protection, accelerate innovation, and reinforce the role of university hospitals as essential drivers of healthcare improvement and scientific progress.

Such a framework would support the objectives of the MDR while contributing to a more competitive, innovative, and collaborative European health ecosystem.