VDGH
Verband der Diagnostica-Industrie

AI-Enabled In Vitro Diagnostics, AI-Enabled Research Products and Research on AI: VDGH Feedback on the Simplification – digital package and omnibus

Seventy per cent of all treatment decisions are based on laboratory diagnostic results. Digital innovations in the field of in vitro diagnostics (IVD), which incorporate algorithms in their development, as a safety component or usage, enable earlier disease detection, personalised treatment approaches and improved patient outcomes. Algorithms are also becoming increasingly integrated into life science research products. These AI-enabled products are enabling technologies used at an early stage in the innovation chain. While they do not make clinical decisions directly, they are indispensable for the discovery and validation of new diagnostics and therapies. Therefore, an innovation-friendly regulatory framework for artificial intelligence enabled in vitro diagnostics and research products is of vast importance.

AI-Enabled In Vitro Diagnostics

The Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) has established itself as a robust framework for patient safety. Its implementation has tightened not only quality requirements but also administrative burdens which especially are difficult to cope for small and medium sized companies. According to the IVDR, diagnostics must deliver consistent and reproducible measurement results under the same conditions. Obligations regarding repeatability, reproducibility and quality assurance are clearly set out in the IVDR. These are core components of the essential performance requirements set out in Annex I, Chapter II, Section 9.1 of the IVDR. Annex I, Chapter II, Section 16.1 of the IVDR further specifies that software must be designed in such a way that repeatability, reliability and performance in accordance with its intended use are ensured. The IVDR therefore comprehensively regulates and protects AI-enabled IVD from arbitrary results. These IVD will, however, now be subject to the more extensive regulatory requirements of the AI Act, which poses a significant barrier to innovation and delays the launch of life-saving diagnostics to market.

As part of its revision of the IVDR/MDR in December 2025, the European Commission proposed moving the IVDR/MDR from Annex I, Section A to Section B of the AI Act. The proposal further states that the relevant AI requirements will be integrated into Annex I of the IVDR/MDR through implementing acts. The VDGH welcomes this step. AI-enabled IVD should be regulated in a consistent and streamlined manner within sector-specific legislation. The AI Act revision, however, must now set the right signals for the IVDR revision by solving a key regulatory issue of AI-enabled IVD.

These include products that comply with all relevant aspects of the IVDR but remain unchanged after being placed on the market and still fall under the definition of AI-Systems according to Art. 3 AI-Act.

Therefore, Germany’s Diagnostics Industry Association (VDGH) proposes specific solutions:

- Exemption of the AI-Act for in vitro diagnostics that comply with the IVDR framework, that may fall under the definition of an 'AI system' according to the AI-Act Art. 3, but do not exhibit adaptiveness after deployment. The VDGH strongly recommends therefore a new paragraph 13. in Art. 2 of the AI Act as follows:
  "*This regulation does not apply for AI systems covered by the Union harmonisation legislation listed in Annex I that do not exhibit adaptiveness after deployment".*

Solutions for AI-Systems that show adaptiveness after deployment:

- Recognise existing safety measures of the IVDR: IVD already undergo strict conformity assessment procedures. Any additional AI-specific requirements must clearly demonstrate added value for patient safety before they are subject to IVD under the IVDR framework.

AI-Enabled Research Products

Research activities in healthcare are already governed by a dense framework of Union law, including the GDPR (with its specific rules for scientific research), the Clinical Trials Regulation and sectoral data-protection as well as cybersecurity rules. Given the importance of promoting the development of new health technologies, it is crucial that the AI Act explicitly exempts AI systems, models and outputs when they are being developed, tested or used for research and development purposes. As outlined in Article 2(6) and Article 2(8) of the AI Act, this exemption is specified therein. However, this exemption does not cover commercial research and development, nor AI-enabled research products placed on the market, leaving them subject to the Act's full compliance regime.

This has a substantial impact on tools in the research phase, with the potential to delay or prevent the development of new diagnostics and treatments. Activities affected include AI-driven research in healthcare, which is often carried out in public–private partnerships with the explicit aim of developing marketable diagnostics, pharmaceuticals, and personalised therapy options. For the VDGH, the AI Act's overarching goal of protecting health and safety is thereby undermined.

The VDGH therefore strongly recommends amending the following paragraphs of Article 2 of the AI Act:

- Art. 2, paragraph 6:
  "*This Regulation does not apply to AI systems or AI models, including their output, specifically developed, put into service* ***or placed on the market*** *for the sole purpose of scientific research and development*."
- Art. 2, paragraph 8:
  "*This Regulation does not apply to any research, testing or development activity regarding AI systems or AI models prior to their being placed on the market or put into service. Such activities shall be conducted in accordance with applicable Union law. Testing in real world conditions shall not be covered by that exclusion.* ***This exception shall be further extended to AI systems and AI models, together with their outputs, that are developed, tested or used for research and***

development purposes, including commercial research and development, covering all stages of scientific and applied research, from industrial research to experimental development."

The German Diagnostics Industry is calling for the clear prioritisation of AI-specific regulations within the existing regulatory framework for medical devices (IVDR/MDR). Moreover, the VDGH seeks an exemption for commercially used AI-enabled research products from the scope of the AI Act. It is only through the elimination of non-essential regulatory constraints that innovations can be delivered to patients in a timely manner, thereby enabling the full potential of diagnostics and research for healthcare.

Patient safety must be at the heart of all considerations. An efficient, consistent regulatory framework ensures both safety and innovation for the benefit of patients across Europe.

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