AI in healthcare policy paper

On 16 December 2025, the European Commission published the Health Package,[1] encompassing two legislative proposals: the targeted revision of the Medical Devices Regulations (MDR/IVDR) and the Biotech Act. These proposals introduce much-needed simplification measures for medical technology and to foster the use of AI and data in health biotechnology. **DIGITALEUROPE broadly welcomes these measures, as they reflect the recommendations outlined by our Health Executive Council.**[2]

As the Health Package proposals move into the ordinary legislative procedure, **this position paper outlines DIGITALEUROPE's recommendations to co-legislators to ensure that these proposals maintain the right level of ambition**, foster a more digital, competitive, and patient-centric healthcare ecosystem, especially on AI-related provisions.

As they negotiate these legislations, the European Parliament and Council of the EU should:

- **Support the European Commission's proposed amendment to the AI Act within the MDR/IVDR** targeted revision (moving MDR/IVDR from Section A to Section B of AI Act Annex I), and further **fine-tune it by clarifying a timeline for the integration of respective high-risk obligations into MDR/IVDR** (see pages 4-5) via delegated acts;
- **Better align the Biotech Act with the AI Act**, as well as further clarify its data-sharing requirements and modalities with those outlined in the EHDS to ensure legal clarity across legislation;
- **Avoid overly broad disclosure requirements on AI uses in the context of clinical trials** when these do not pose risk to patients or have high regulatory impact & **ensure guidelines on AI use in Biotech and clinical trials are closely developed with industry**;
- **Support and further refine the** European Commission proposed **amendments** to the **Clinical Trials Regulation (CTR)** around the **legal basis for processing health data in** the context of **clinical trials**;

The document further provides a list of amendments to the proposed MDR/IVDR revision that would support a more balanced classification of software as a medical device and would facilitate the digitalisation of healthcare more broadly**.** These can be found in the Annex.

[1] More information on the Health Package is available at https://commission.europa.eu/news-and-media/news/commission-proposes-new-measures-improve-health-and-healthcare-sector-2025-12-16_en

[2] See DIGITALEUROPE, *The Executive Brief Health Executive Council*, available at https://cdn.digitaleurope.org/uploads/2025/11/DIGITALEUROPE-TheExecutiveBrief5-HealthCouncil_V09-04112025-pbp.pdf

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AI in Medical Devices Regulation & In-vitro Diagnostics Regulation

AI-powered medical technologies have long been regulated under the EU Medical Devices Regulation (MDR)[3] and the In Vitro Diagnostic Regulation (IVDR),[4] which apply to all medical technologies, including software, irrespective of whether it uses traditional algorithms or AI/ML techniques. Where software has a medical intended purpose, such as diagnosis, prediction, monitoring, or treatment, it qualifies as a medical device and must comply with the full set of MDR/IVDR requirements. **These include the General Safety and Performance Requirements (Annex I), clinical or performance evaluation obligations (e.g. MDR Article 61, IVDR Article 56), comprehensive risk management** throughout the lifecycle, quality management systems, and post-market surveillance. As such, AI-powered medical technologies are already subject to strict conformity assessment, validation, documentation, and safety oversight.

While the AI Act was introduced with the commendable goal of ensuring legal certainty for AI development and use in Europe, its adoption has also prompted further reflection on how horizontal AI requirements should interact with existing sectoral regulatory frameworks. In sectors such as medical technologies, where detailed legislation already governs product safety, performance and lifecycle oversight, ensuring a coherent regulatory interaction is essential. In this context, the sector-agnostic nature of the AI Act has raised a number of practical questions for medical technology manufacturers regarding how certain concepts introduced by the Regulation relate to those already established under the MDR and IVDR. In particular, differences in terminology, approaches (e.g. on risk management), regulatory triggers between the two frameworks have raised uncertainty about how compliance should be assessed and implemented in practice. Some of these misalignments are:

- **The AI Act introduces the concept of "substantial modification"** defined as a change to an AI system after its placing on the market or putting into service that was not foreseen in the initial conformity assessment and that either (i) affects compliance with the Act's requirements or (ii) modifies the system's intended purpose. Under Article 25(1)(b), such a modification may transfer provider obligations to the entity making the change, including the need for a new conformity assessment. **This concept is not aligned with the MDR/IVDR framework, which instead uses "significant change"** (and, in some contexts, "substantial change") **as the trigger for regulatory action.**
- **Another example of unresolved incompatibility concerns risk management**. **The concept of "risk" exposes a structural inconsistency between the AI Act and the MDR/IVDR**. While the AI Act requires risks to be reduced "as far as technically feasible," the MDR and IVDR rely on a benefit–risk balance, essential to healthcare delivery, that accepts justified risks in light of clinical benefit. The scope of risk within MDR and IVDR is focused on the definition of harm to patients or the surrounding environment. The risk definition under the AI Act also includes fundamental rights, but they remain largely unspecific for medical technologies. This creates uncertainty in the risk management process and may lead to variability in interpretation, including among notified bodies. The AI Act expansion of risk management to fundamental rights, adds reporting obligations and parallel assessment layers without clear guidance on how these considerations interact with established clinical risk frameworks.

[3] Regulation (EU) 2017/745. More information on MDR available at https://eur-lex.europa.eu/eli/reg/2017/745/oj/eng

[4] Regulation (EU) 2017/746. More information on IVDR available at https://eur-lex.europa.eu/eli/reg/2017/746/oj/eng

- **AI Act's effective implementation depends on harmonised standards that are unlikely to be available in time** and whose alignment with the MDR/IVDR remains unresolved. Divergent definitions and concepts create structural inconsistencies between the frameworks and will render the utility of the standards as compliance tool limited for the entire sector of medical technologies. Experience to date with the interpretation of certain core definitions and compliance obligations under the AI Act has prompted extensive dialogue among regulators and stakeholders and required substantial regulatory and industry engagement. This highlights the importance of ensuring that the interaction between a horizontal AI framework and the existing regulatory framework for medical devices is carefully managed, in order to avoid potential impacts on development timelines, market access, and innovation in the health sector.

Regulatory complexity remains one of the most significant barriers to innovation in Europe. Even when cutting-edge technologies are developed within the EU, they frequently reach patients in other regions first. Compared to the previous framework, the current MDR and IVDR have led to longer average certification timelines for (including AI-enabled ones) medical devices,[5] higher conformity assessment costs, and increased regulatory staffing requirements. The addition of overlapping and inconsistent obligations under the AI Act risks further widening Europe's innovation gap in AI, prolonging patient access to innovative technologies and undermining the competitiveness of European companies.

DIGITALEUROPE welcomes the European Commission's efforts to simplify the regulatory landscape[6]. The proposed targeted simplification of the MDR/IVDR introduces measures to ensure a streamlined, faster, and more coherent regulatory framework for medical devices and diagnostics. Notably, with regard to AI-powered devices, the proposal puts forward an important amendment by moving **MDR/IVDR from Section A to Section B of Annex I of the AI Act**. **This ensures that devices and diagnostics deemed high-risk AI systems or use high-risk AI systems as safety components as per AI Act are regulated under one coherent regulatory pathway: their respective sectoral Regulation.** This approach ensures the safety and performance of AI-enabled medical technologies while avoiding unnecessary duplication of unsuitable obligations for the sector. This approach was already applied to other sectors in Annex I Section B of the AI Act and was recently extended to machinery in the recent AI Omnibus agreement. It constitutes genuine regulatory simplification because **the substantive requirements related to high-risk AI systems would remain fully in place** but would be embedded within the revised MDR/IVDR. To ensure legal certainty for manufacturers and maintain the legal playing field for all manufacturers of AI-enabled technologies, the AI Act must remain a maximum-harmonisation instrument – ensuring that sector-specific measures (secondary legislation or technical specifications) do not add to, or expand beyond, AI Act requirements.[7] This would avoid regulatory gold-plating and preserve a consistent understanding of 'state of the art' across sectors.

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[5] Lessons from the transition from the Medical Device Directives (MDDs) to the Medical Devices and In Vitro Diagnostics Regulations (MDR/IVDR) are telling: **certification times doubled from 9–12 to 12–24 months, whilst costs rose by 260%**. See: https://cdn.digitaleurope.org/uploads/2025/11/DIGITALEUROPE-TheExecutiveBrief5-HealthCouncil_V09-04112025-pbp.pdf

[6] Art(s). 1(5)(b) and (8) of the proposed amendment to the MDR, and 2(5)(b) and (8) of the proposed amendment to the IVDR, empower the European Commission to adopt delegated acts to amend the GSPRs set out in Annex I of the MDR and IVDR, in order to integrate relevant requirements from the AI Act. Article 4 amends Annex I of the AI Act by moving references to the MDR and IVDR from Section A to Section B.

[7] For more on DIGITALEUROPE's position on the AI Act, see https://cdn.digitaleurope.org/uploads/2026/02/AI-omnibus-a-necessary-pause-to-enable-real-simplification.pdf

DIGITALEUROPE thus supports the Commission's proposed amendment to the AI Act in the MDR/IVDR targeted revision and believes it could be further fine-tuned by clarifying the timeline for the integration of the respective high-risk obligations into the MDR/IVDR.

We therefore propose adding an additional clarifying recital and two paragraphs under Articles 1(5)(b)(7-8) of the MDR and 2(5)(b)(7-8) of the IVDR:[8]

Recital (23a)	
EC proposal	Amendment
Recital 23 […] Where needed the Commission may use its implementing and delegated powers to lay down specific requirements regarding artificial intelligence, taking into account the requirements set out in Chapter III, Section 2, of Regulation (EU) 2024/1689. Moreover, notified bodies that are designated to assess high-risk AI systems falling under Regulations (EU) 2017/745 or (EU) 2017/746, as applicable, should meet also the specific AI-related requirements set out in Article 31 of Regulation (EU) 2024/1689.	***Recital 23a*** ***In order to ensure a coherent regulatory framework for medical devices and in vitro diagnostic medical devices which use artificial intelligence, the relevant requirements of the Regulation (EU) 2024/1689 set out in Chapter III, Section 2, of that Regulation should be integrated into the general safety and performance requirements set out in Annex I of the Regulations (EU) 2017/745 and (EU) 2017/746 in a manner that ensures consistency with the requirements of Annex I. Such integration should avoid duplication and inconsistency of obligations for manufacturers and ensure that the integrity of conformity-assessment procedures provided for in Regulations (EU) 2017/745 and (EU) 2017/746 is maintained and they remain the primary mechanism for demonstrating compliance of those devices, including with the relevant requirements concerning artificial intelligence. Where the Commission adopts implementing or delegated acts specifying such requirements, those measures should ensure alignment with the requirements set out in Chapter III, Section 2, of Regulation (EU) 2024/1689 and reflect those requirements in a manner that supports their consistent application within the sectoral framework, thereby preserving legal certainty for manufacturers and maintaining coherence across sectors within the scope of Regulation (EU) 2024/1689***.

Amendments to Regulation (EU) 2017/745 Article 5 paragraph 8a (new)	
EC proposal	Amendment (additional paragraph)
(b) the following paragraph 7 is added: '7. The Commission is empowered to adopt delegated acts in accordance with Article 108, to amend the general safety and performance requirements set out in Annex I in order to adapt	[…] ***8a*** ***The Commission shall, within 12 months of [the date of entry into force of this Regulation], adopt a delegated act to amend the general***

[8] 25e7ea7c-cab3-40cf-86d9-d11f5e7744d8_en

them to scientific or technical progress or to international developments, or to add requirements in relation to emerging risks or technologies. 8. When adopting implementing acts pursuant to paragraph 6 of this Article, delegated acts pursuant to paragraph 7 of this Article or Common Specifications pursuant to Article 9 of this Regulation concerning devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council**, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation.	***safety and performance requirements set out in Annex I to this Regulation to integrate the relevant requirements concerning devices deemed high-risk AI systems under Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, set out in Chapter III, Section 2, of that Regulation.*** ***Where the Commission adopts such delegated act specifying such requirements, those measures should ensure alignment with the requirements set out in Chapter III, Section 2, of Regulation (EU) 2024/1689 and reflect those requirements in a manner that supports their consistent application within the sectoral framework.***

Amendments to Regulation (EU) 2017/746 Article 5 paragraph 8a (new)	
EC proposal	**Amendment (additional paragraph)**
(b) the following paragraph 7 is added: '7. The Commission is empowered to adopt delegated acts in accordance with Article 108, to amend the general safety and performance requirements set out in Annex I in order to adapt them to scientific or technical progress or to international developments, or to add requirements in relation to emerging risks or technologies. 8. When adopting implementing acts pursuant to paragraph 6 of this Article, delegated acts pursuant to paragraph 7 of this Article or Common Specifications pursuant to Article 9 of this Regulation concerning devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council**, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation.	***8a*** ***The Commission shall, within 12 months of [the date of entry into force of this Regulation], adopt a delegated act to amend the general safety and performance requirements set out in Annex I to this Regulation to integrate the relevant requirements concerning devices deemed high-risk AI systems under Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, set out in Chapter III, Section 2, of that Regulation.*** ***Where the Commission adopts such delegated act specifying such requirements, those measures should ensure alignment with the requirements set out in Chapter III, Section 2, of Regulation (EU) 2024/1689 and reflect those requirements in a manner that supports their consistent application within the sectoral framework.***
Justification	
The language outlined above retains the Commission's original intention to integrate AI Act provisions into the MDR/IVDR via delegated acts, while already providing legal clarity on the specific timeline by which they should be incorporated as a matter of priority. This would ensure clarity for manufacturers and uphold the highest level of relevant safety standards provided by the AI Act. **It should also be noted that this approach allows for necessary adjustments to be made in the future through delegated acts** (as reflected in the current text of the proposal retaining continuous interaction with the further evolution of the AI Act, cf. Art. 1(5)(b)(8) of the MDR and 2(5)(b)(8) of the IVDR), **taking into account technological and scientific developments, in line with the Commission's proposal.** This approach preserves safety by filling existing regulatory gaps within MDR/IVDR with relevant AI Act provisions, avoids misalignment, conflicting approaches and lack of legal clarity around diverging definitions across regulations and maintains the integrity of one coherent assessment procedure (via notified bodies	

designated under MDR/IVDR). Furthermore, the addition of a deadline for adoption of the delegated acts ensures that there will be no regulatory vacuum to address these gaps.

Finally, in light of the recent agreement on the AI Omnibus, it is important to note that its proposed measures do not resolve the challenges outlined above, arising from the interaction between the AI Act and the MDR/IVDR. On the contrary, they risk introducing additional complexity and legal uncertainty. The mechanism for determining an equivalent level of protection remains undefined and would, in any event, depend on the MDR/IVDR providing protections equivalent to those of the AI Act: the very objective pursued by the amendments proposed in this paper (in line with Commission's approach in MDR/IVDR). Rather than enhancing coherence between the frameworks, this approach prolongs uncertainty and creates further regulatory fragmentation.

AI and Data in the Biotech Act and amended Clinical Trials Regulation

The proposed Biotech Act introduces new provisions while also putting forward important simplification measures to the Clinical Trials Regulation (CTR),[9] among other regulations. **DIGITALEUROPE broadly supports the measures aimed at encouraging the use of AI to foster biotech research, commercialisation, and its application in clinical trials**. That said, it is essential that the Biotech Act does not introduce definitions that conflict with or contradict those established under the AI Act. Overall, there is a terminology consistency issue within parts of the Biotech Act, as the proposal alternates between references to "AI models" and "AI systems". It should be noted that only "AI system" and "General-Purpose AI model" are defined under the AI Act. The absence of a clear definition for "AI model," combined with inconsistent terminology, may lead to interpretative challenges, misalignment with the AI Act taxonomy, and legal uncertainty for regulators and developers. As the proposal advances through the ordinary legislative procedure, **co-legislators should address the existing misalignment with the terminology of the AI Act to enhance legal clarity and coherence within the Biotech Act.**

DIGITALEUROPE also welcomes the proposed clarifications regarding the harmonisation of the GDPR legal basis for the processing of special categories of personal data with a view to ensuring faster and more streamlined clinical trials in the EU.

AI and Data as Biotechnology Enablers

Article 31 empowers the European Medicines Agency (EMA) to issue guidance on the deployment and use of systems based on advanced technologies, including AI, throughout the lifecycle of medicinal product development, including pre-clinical research, clinical development, manufacturing, and post-authorisation monitoring.[10] **It is important that these guidelines are developed in open collaboration with**

[9] Regulation (EU) No 536/2014. More information on CTR available at https://eur-lex.europa.eu/eli/reg/2014/536/oj/eng

[10] These guidelines should also avoid blanket prohibitions that deviate from the established regulatory norms, where risk-based approaches prevail. For instance, the recently proposed. The European Medicines Agency's (EMA) recent Annex 22 AI proposal (5f38a92d-bb8e-4264-8898-ea076e926db6_en) exemplifies this challenge. The ban could hinder pharmaceutical innovation and limit manufacturers' ability to use proven technologies that enhance drug quality and safety. Furthermore, it overlooks the capability of properly validated AI systems to meet or exceed existing GMP requirements and risks restricting EU access to medications developed with AI technologies in other regions. This approach threatens to place the EU at a significant disadvantage in global

stakeholders, including industry, and take into account already existing work being conducted by the European Medicines Agency. Furthermore, the guidelines should be developed in full consideration of, and alignment with, the R&D exemption guidance being prepared by the AI Office as part of the Digital Omnibus non-legislative initiatives. To ensure that these points are properly reflected in the legislation, as well as to maintain alignment with definitions under the AI Act and ongoing regulatory work on this matter, we suggest the following amendments:

Article 31	
EC proposal	**Amendment**
(1) The Agency shall publish and regularly update, as appropriate, non-binding guidance on the deployment and use of systems based on advanced technologies, including AI, in the lifecycle of medicinal products development, including during pre-clinical research, clinical development and trials, manufacturing and post-authorisation monitoring. Such guidance shall be developed, updated and published in agreement with the Commission, including with the AI Office. Such guidance shall ensure full coherence with the requirements laid down in Regulation (EU) 2024/1689 and with any guidance issued under that Regulation regarding general-purpose AI models or AI systems.	(1) The Agency, ***following stakeholder consultation***, shall publish and ~~regularly~~ update, as appropriate, non-binding guidance on the deployment and use of systems based on ***general-purpose AI models*** or ***AI systems***, in the lifecycle of medicinal products development, including during pre-clinical research, clinical development and trials, manufacturing and post-authorisation monitoring. Such guidance shall be developed, updated and published in agreement with the Commission, including with the AI Office and ***aligned with domain specific guidance on AI listed in EMA/HMA workplans.*** Such guidance shall ensure full coherence with the requirements laid down ***in this Regulation and*** Regulation (EU) 2024/1689 and with any guidance issued under that ***Regulation*** regarding general-purpose AI models or AI systems.
Justification	
The amendment better aligns proposed Article on non-binding guidance on AI with existing workstreams in the EMA as well as clearly requires stakeholder consultation as part of the process. Furthermore, it better aligns the terminology with that of the AI Act (e.g. General-purpose AI models and AI systems)	
EC proposal	**Amendment**
(2) In developing and updating the guidance referred to in paragraph 1, the Agency shall consult the relevant authorities, at national and European level, and stakeholders as appropriate. To the extent that the guidance concerns the deployment and use of systems based on advanced technologies, including AI, across the clinical trials lifecycle, the Agency shall further cooperate with [...]	In developing and updating the guidance referred to in paragraph 1, the Agency shall consult the relevant authorities, at national and European level, and stakeholders ~~as appropriate~~, ***including providers and deployers of AI.*** To the extent that the guidance concerns the deployment and use of systems based on ***general-purpose AI models and AI systems***, across the clinical trials lifecycle, the Agency shall further cooperate with […]
EC proposal	**Amendment**
(3) The Agency shall develop and publish in agreement with the Commission, including the AI Office where appropriate, and in cooperation with the national competent authorities, non-binding guidance on the deployment and use of advanced	(3) The Agency shall develop and, ***following stakeholder consultation***, publish in agreement with the Commission, including the AI Office where appropriate, and in cooperation with the national competent authorities, non-binding

pharmaceutical development and manufacturing, potentially impacting patient access to innovative treatments.

technologies, including AI, in the procedures for the authorisation of medicinal products.	guidance on the deployment and ~~use of advanced technologies~~, including ***general-Purpose AI models and AI systems***, in the procedures for the authorisation of medicinal products by ***the Agency and national competent authorities***.
Justification	
The amendments above better align the proposed Articles on non-binding guidance on AI with existing workstreams in the EMA and the AI Office, as well as clearly requires stakeholder consultation as part of the process. Furthermore, it better aligns the terminology with that of the AI Act (e.g. general-purpose AI models and AI systems)	

Articles 32 and 33 provide relevant incentives for the use of AI or advanced computational methods in biotechnology, particularly for the collection and maintenance of high-quality data essential for biotechnology applications. **To ensure the protection of investments made by health data holders in collecting and curating such data—and for reasons of consistency—this data should be protected at least to the same standard as electronic health data covered by the EHDS (Article 52(3)**). Particularly important is ensuring that **access principles** and security safeguards (as set out in Article 16) **include appropriate and proportionate legal, organisational, and technical measures to protect intellectual property, trade secrets, and regulatory data protection rights**. These measures will safeguard innovation incentives and prevent unintended disclosure when data or results are shared via accelerators, testing environments, or sandboxes. While Article 33 acknowledges EHDS, these references mainly concern the definition of health data holder, data quality and unclear language "give due considerations to the interoperability with platforms deployed pursuant to the EHDS […]". To ensure legal coherence and avoid regulatory fragmentation, the Article 33 should include explicit alignment clauses linking the access principles and security safeguards to take into consideration, when relevant, the protective measures outlined in the EHDS Regulation. At the same time, such alignment with the EHDS should not make it the exclusive lawful route for accessing, sharing or otherwise processing health data for biotechnology, clinical research or related innovation purposes. The Biotech Act should preserve other lawful mechanisms, including authorised clinical trials, contractual research arrangements, regulatory obligations, public-health frameworks and other applicable Union or Member State laws, provided that appropriate safeguards apply. The following proposed amendments would provide further coherence across legislation:

Article 33	
EC proposal	Amendment
(6) Entities that lawfully hold relevant datasets enhanced as provided for in paragraph 2, point (b) of the Article, shall support, where appropriate, the integration of such datasets into Union infrastructures, including the European Research Area data spaces, data labs, AI factories and the infrastructures operated by high impact health biotechnology strategic projects.	(6) Entities that lawfully hold relevant datasets enhanced as provided for in paragraph 2, point (b) of the Article, shall support, where appropriate, the integration of such datasets into Union infrastructures, including the European Research Area data spaces, data labs, AI factories and the infrastructures operated by high impact health biotechnology strategic projects, ***under the conditions referred to in Article 16 of this Regulation provided that such Union infrastructures comply with the technical, interoperability, and security safeguards established under Regulation (EU) 2025/327 (European Health Data Space), including legal, organisational and technical nature to protect***

	intellectual property and trade secrets. Data holders shall not be required to integrate datasets into any Union infrastructure that does not conform to these technical and security specifications.
Justification	
The EHDS already provides for clear mechanisms to access electronic health data, also relevant for biotech innovation, and sets out requirements protection measures, including around IP and trade secret, on how said data is to be shared. Alignment between Biotech Act and EHDS is needed to ensure trust and legal clarity for innovators.	

Article 39 of the Biotech Act provides for the coordination of regulatory sandboxes established under applicable Union frameworks through cross-framework communication facilitated by the Foresight Panel in Article 37. This allows for coordination between pharma legislation, MDR/IVDR, and AI Act, with the specificities of biotech products. Article 40 provides for an additional possibility of establishing sandboxes directly via the Biotech Act, if these cannot be accommodated by existing sandboxes. It is important that the functioning of these sandboxes is clear, aligned with existing sandboxes provided under other regulations to avoid legal uncertainty and fragmentation. **Clarity should also be provided to innovators regarding which sandbox applies in a given scenario and which authority oversees its operationalisation.**

Article 52 (4) allows the Advisory Group on Biosecurity to issue a qualified alert to the European Commission and Member States if it has grounds to suspect that an AI model in a biological application is **not** covered by the AI Act and poses biological system risk. However, the AI Act already establishes a comprehensive framework for classification and governance of AI systems and GPAI models based on their risk level: **Article 52(4) should therefore be clarified or deleted to avoid creating a parallel AI-risk classification mechanism outside the AI Act**. Any alert mechanism should be limited to coordination with the AI Office and relevant competent authorities and should not create independent obligations, classifications, or restrictions beyond the AI Act and applicable sectoral legislation.

Amendments to the Clinical Trials Regulation

Parallel substantial modifications (Article 58 (23))

Article 58(23) introduces the possibility of including, as supporting evidence in clinical trial applications or in requests for substantial modifications, health data accessed under the EHDS Regulation. However, it is important to recognise that such data may also be obtained through other lawful mechanisms.

Art. 58(23) **Amendments to Regulation (EU) No 536/2014: Article 16a Parallel substantial modification**	
EC proposal	**Amendment**
(d) (8) An application dossier for an authorisation of a clinical trial or for an authorisation of a substantial modification may rely on health data accessed under Chapter IV of Regulation (EU) 2025/327 of the European Parliament and of the Council*	(d) '8. An application dossier for an authorisation of a clinical trial or for an authorisation of a substantial modification may rely on health data ***from sources outside the clinical trial, including data*** accessed under Chapter IV of Regulation (EU) 2025/327 of the European Parliament and of the Council

Justification
The amendment clarifies that the provision does not imply that EHDS access is the only pathway for obtaining relevant health data.

Sandboxes and AI guidelines for clinical trials

In the proposed amendments to the CTR, a number of provisions address the use of AI in clinical trials. **DIGITALEUROPE supports what is proposed in the newly added Chapter IVb which creates the possibility for the Commission to establish regulatory sandboxes for innovative clinical trials.** In this Chapter, the authorisation and conduct of clinical trials could, where appropriate, be coordinated with AI regulatory sandboxes established under the AI Act. To ensure that these sandboxes deliver on their intended purpose of accelerating the development and testing of novel approaches, the **European Commission should conduct regular assessment of their effectiveness and added value.** Such a requirement would help ensure that these instruments remain fit for purpose, proportionate, and supportive of innovation in practice. It would also provide stakeholders with greater legal certainty and confidence that regulatory sandboxes generate measurable added value and effectively contribute to the objectives of the Regulation. Furthermore, Article 27d introduces the possibility of establishing a regulatory sandbox aimed at increasing the efficiency of clinical trials. However, the efficiency of clinical trial processes primarily concerns trial sponsors and developers in the design and conduct of their studies. It should not fall within the remit of the European Medicines Agency (EMA), whose mandate is to assess the quality, safety and efficacy of medicines, conduct benefit–risk evaluations, monitor medicines, and support related regulatory decision-making. We therefore suggest amending Article 27d (b) (ii) as follows:

Art. 58(24) Amendments to Regulation (EU) No 536/2014: Article 27d	
EC proposal	**Amendment**
(b) the approaches referred to in point (a) are expected to contribute to at least one of the following objectives: [...] (ii) considerably decreasing clinical trial length, and increasing the efficiency of the clinical trial;	(b) the approaches referred to in point (a) are expected to contribute to at least one of the following objectives: [...] (ii) considerably decreasing clinical trial length, and ~~*increasing the efficiency of the clinical trial*~~; ***9) The Commission shall assess the effectiveness and added value of the regulatory sandboxes every two years and publish its findings.***
Justification	
The efficiency of clinical trial processes primarily concerns trial sponsors and developers in the design and conduct of their studies. It should not fall within the remit of the European Medicines Agency (EMA), whose mandate is to assess the quality, safety and efficacy of medicines. It is also important that to foster use of regulatory sandboxes, their added value is regularly assessed.	

Article 27e (Article 58(24) (e)) also requires sponsors to disclose how AI is being used in the context of a trial. **Considering the broad use of AI in clinical trials, including in cases where there is no regulatory impact or patient risk, the language of this Article should avoid overburdening regulators with reports of AI uses that have little or no regulatory relevance**—for instance, AI used purely to improve

the wording of documents relevant to clinical trials, with a human-in-the-loop as final author. In its Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle,[11] the EMA recognised that there is already a well-established understanding of how AI may impact patient safety, data robustness, and regulatory decision-making. Using language that is consistent with EMA guidance is essential to ensure legal clarity, regulatory predictability, and coherence within the EU medicines framework. It helps avoid the introduction of parallel or potentially conflicting concepts that could lead to inconsistent interpretation or duplicative requirements across Member States. **Moreover, anchoring the assessment of AI use to a context-specific, risk-based approach, as outlined by the EMA, ensures that sponsors focus on AI applications that may have a meaningful impact on patient safety or regulatory outcomes, while avoiding unnecessary burden for low-risk uses**. This approach supports innovation while maintaining high standards of protection and oversight, in line with existing EU medicines legislation and regulatory practice. As such, we suggest **the following amendments to the newly added Article 27e:**

Art. 58(24) **Amendments to Regulation (EU) No 536/2014: Chapter IVb - Article 27e**	
EC proposal	**Amendment**
(1)For those clinical trials where the sponsor plan to use AI models or systems, the sponsor shall evaluate the benefits and risks related to patient safety and data robustness of the use of the AI in the context of a specific clinical trial for a specific purpose taking into account the guidelines laid down in Article 37 of Regulation [...] [Biotech Act]. (2) The sponsor shall provide information in the protocol on the specific purpose of the use of AI models or systems and the description of the process in the context of the specific clinical trial.	~~1. For those clinical trials where the sponsor plan to use AI models or systems, the sponsor shall evaluate the benefits and risks related to patient safety and data robustness of the use of the AI in the context of a specific clinical trial for a specific purpose taking into account the guidelines laid down in Article 37 of Regulation [...] [Biotech Act]. of the AI~~ 1. ***The sponsor shall assess whether the specific context of use of AI models or systems used in clinical trials may pose a high risk to patients or high regulatory impact*** in the context of a specific clinical trial for a specific purpose taking into account the guidelines laid down in Article 37 of Regulation [...] [Biotech Act]. 2. The sponsor shall provide information in the protocol on the specific purpose of the use of AI models or systems ***that have been assessed as posing a high risk to patients or high regulatory impact*** and the description of the process in the context of the specific clinical trial, ***taking into consideration guidance proposed in Article 31.***
Justification	
Given the wide use of AI in clinical trials, including in low-risk or non-regulatory contexts, the Article should avoid imposing disproportionate reporting obligations for uses with no meaningful impact (e.g. AI-assisted drafting with human oversight). Aligning the language with EMA guidance would ensure legal clarity, regulatory coherence, and consistency across Member States. A risk-based, context-	

[11] See EMA, *Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle*, available at https://www.ema.europa.eu/system/files/documents/scientific-guideline/reflection-paper-use-artificial-intelligence-ai-medicinal-product-lifecycle-en.pdf

specific approach would focus requirements on AI uses relevant to patient safety and regulatory decision-making, while avoiding unnecessary administrative burden.

Furthermore, Annex II (d) also presents a related reference on the use of AI in clinical trials which requires re-wording to ensure a more sensible risk-based approach, which should be reworded as:

Annex I D	
EC proposal	**Amendment**
(aq) if the sponsor used an AI tool, a clear explanation of the specific purpose of the use of that tool and a description of the processes in which it is used. If an AI tool is certified according to Regulation (EU) 2024/1689 laying down harmonised rules on artificial intelligence, the sponsor shall provide the information contained in the certificate.	(aq) if the sponsor used a ***general-purpose AI model or AI system in a clinical trial that may carry high patient risk or have high regulatory impact***, a clear explanation of the specific purpose of the use of that tool and a description of the processes in which it is used. If an AI tool is certified according to Regulation (EU) 2024/1689 laying down harmonised rules on artificial intelligence, the sponsor shall provide the information ***in the accompanying cover letter submitted together with the clinical trial application*** ~~contained in the certificate.~~
Justification	
As per Article above	

CTR and the GDPR

Proposed amendments in the Commission proposal to the CTR also provide important clarifications regarding the **legal basis for processing personal data, including genetic data and data concerning health, in the context of clinical trials**. Specifically, Article 58(48) amends the CTR by introducing several key provisions to clarify that the processing of special categories of personal data in clinical trials takes place for reasons of public interest in the area of public health, with the objective of ensuring high standards of medicinal products, pursuant to Article 9(2)(i) of the GDPR. Crucially, in order to address the fragmentation of clinical trials resulting from divergent GDPR enforcement, **Member States will no longer be permitted to maintain or introduce further conditions, limitations, or specific provisions under Article 9(4)** of the GDPR regarding the processing of personal data, including genetic data and data concerning health. Another important measure proposed to support clinical trials is that personal data collected under an authorised protocol may be processed by the same controller for other authorised clinical trials. **DIGITALEUROPE welcomes these proposed changes, and they should be maintained during the co-legislative procedure**, as they deliver much-needed clarity and harmonisation across the EU in relation to personal data processing for clinical trials. That said, DIGITALEUROPE suggests targeted amendments to ensure a more balanced approach to further processing. The current wording would limit further processing to the sponsor of the trial, despite the fact that the sponsor may not be the only entity engaged in scientific research, nor necessarily the primary one.

Article 58 (48) Amendments to Regulation (EU) No 536/2014: Article 93	
EC proposal	Amendment

1; When carrying out their tasks pursuant to this Regulation, sponsors are required to process personal data, including genetic data or data concerning health for the following purposes: a) for the submission of applications in accordance with Articles 5, 11, 14 and 16; b) to perform research activities in the context of a clinical trial in accordance with the protocol as authorised by the national competent authorities in accordance with point D, Part I of Annex I; c) to perform safety operations and reporting in accordance with Articles 41 to 43 and 52 to 54; d) to record, process, handle and store information in accordance with Article 56; e) to perform archiving in accordance with Article 58; f) to submit to the EU portal the summary of the results of the clinical trial, the lay summary, the clinical study report and, where applicable, raw data, in accordance with Article 37(4).	1; When carrying out their tasks pursuant to this Regulation, sponsors are required to process personal data, including genetic data or data concerning health for the following purposes: a) for the submission of applications in accordance with Articles 5, 11, 14 and 16; b) to perform research activities in the context of a clinical trial in accordance with the protocol as authorised by the national competent authorities in accordance with point D, Part I of Annex I; c) to perform safety operations and reporting in accordance with Articles 41 to 43 and 52 to 54; d) to record, process, handle and store information in accordance with Article 56; e) to perform archiving in accordance with Article 58; f) to submit to the EU portal the summary of the results of the clinical trial, the lay summary, the clinical study report and, where applicable, raw data, in accordance with Article 37(4). ***g) to perform monitoring in accordance with Article 48;*** ***h) other activities that are ancillary to and support the sponsors' fulfilment of their obligations pursuant to this Regulation.***
Justification	
In line with paragraph 11 of the European Data Protection Board (EDPB) and European Data Protection Supervisor (EDPS) Joint Opinion on the Biotech Act[12], this amendment introduces a limited residual category to provide legal certainty for processing activities that are necessary and closely linked to sponsors' regulatory obligations. It also reflects the recommendation of the EDPB and EDPS to clarify that processing is permitted where necessary for the purposes set out in Article 93.	
EC proposal	**Amendment**
2. When carrying out their tasks pursuant to this Regulation, investigators are required to process personal data, including genetic data or data concerning health for the following purposes: a) to perform research activities in the context of a clinical trial in accordance with the protocol as authorised by the national competent authorities in accordance with point D, Part I, Annex I; b) to perform safety reporting in accordance with Articles 41 and 54; c) to record, process, handle and store information in accordance with Article 56;	2. When carrying out their tasks pursuant to this Regulation, investigators are required to process personal data, including genetic data or data concerning health for the following purposes: a) to perform research activities in the context of a clinical trial in accordance with the protocol as authorised by the national competent authorities in accordance with point D, Part I, Annex I; b) to perform safety reporting in accordance with Articles 41 and 54; c) to record, process, handle and store information in accordance with Article 56;

[12] https://www.edpb.europa.eu/our-work-tools/our-documents/edpbedps-joint-opinion/edpb-edps-joint-opinion-32026-proposal-european_en

d) to perform archiving in accordance with Article 58	d) to perform archiving in accordance with Article 58 *e)* ***other activities that are ancillary to and support the sponsors' fulfilment of their obligations pursuant to this Regulation***
Justification	
The amendment introduces a limited residual category to provide legal certainty for processing activities that are necessary and closely linked to sponsors' regulatory obligations. It is also consistent with the recommendation of the European Data Protection Board (EDPB) and the European Data Protection Supervisor (EDPS) to clarify that processing is permitted where necessary for the purposes set out in Article 93.	
EC proposal	**Amendment**
4. For the processing assessment leading to the authorisation of clinical trial applications and operations referred to in this Article, sponsors and investigators are controllers within the meaning of Article 4(7) of Regulation (EU) 2016/679.	4. For the processing assessment leading to the authorisation of clinical trial applications and operations referred to in this Article, sponsors and investigators are controllers within the meaning of Article 4(7) of Regulation (EU) 2016/679. ***Sponsors and investigators shall act as independent controllers unless they have substantially collaborated in the development of the protocol. In such case, they shall be joint controllers with respect to the collaboratively developed aspects. Participation in advisory consultations or ethics reviews shall not constitute substantial collaboration. For the purpose of this Article, where an investigator is employed or engaged by a clinical trial site that has entered into a clinical trial agreement with the sponsor, the clinical trial site shall be considered the controller and the investigator shall process personal data under its authority*.**
Justification	
The amendment provides greater legal certainty and harmonisation regarding the allocation of responsibilities under Regulation (EU) 2016/679 (GDPR) in the context of clinical trials. In particular, it clarifies that investigators acting under the authority of a clinical trial site should not be considered controllers in their individual capacity.	
EC proposal	Amendment
6. Personal data collected and processed in accordance with this Regulation may be further processed by the same controller for the purposes of other clinical trials conducted under this Regulation, or for scientific research with the aim of protecting public health, improving standard of care and fostering the innovation capacity of European medical research	6. Personal data collected and processed in accordance with this Regulation may be further processed ~~**by the same controller**~~ for the purposes of other clinical trials conducted under this Regulation**.** ***Such further processing shall be deemed necessary for compliance with Articles 93(1) and 93(2). Subject to the safeguards required under Article 89(1) of Regulation (EU) 2016/679, personal data collected and processed in accordance with this Regulation may also be further processed*** for ***other*** scientific research with the aim of protecting public health, improving standard of care and fostering the innovation capacity of European medical research.

	Such processing shall be deemed necessary for the performance of a task carried out in the public interest in the area of public health within the meaning of Articles 6(1)(e) and 9(2)(i) of Regulation (EU) 2016/679. This paragraph shall not determine the qualification of the parties as controllers, joint controllers or processors under Regulation (EU) 2016/679, which shall be assessed in accordance with that Regulation.
Justification	
Limiting further use to the same controller is unduly restrictive. Under the General Data Protection Regulation (GDPR), entities within the same corporate group are generally separate controllers. The current wording would therefore exclude other group entities and research collaborators involved in scientific research, unnecessarily limiting legitimate secondary research activities. The proposed amendment enables further processing for scientific research purposes subject to the safeguards already provided under the GDPR framework and clarifies the relevant public-interest basis in the area of public health. It also confirms that the allocation of roles as controller, joint controller or processor remains subject to assessment under the GDPR based on the factual circumstances of the processing.	
EC proposal	**Amendment**
7. By derogation from Article 9(4) of Regulation (EU) 2016/679, Member States may not maintain or introduce further conditions, including limitations, with regard to the processing of personal data, including genetic data or data concerning health in the context of clinical trials carried out in accordance with this Regulation	7. By derogation from Article 9(4) of Regulation (EU) 2016/679, Member States may not maintain or introduce further conditions, including limitations, with regard to the processing of personal data, including genetic data or data concerning health in the context of clinical trials carried out in accordance with this Regulation, ***or other research pursuant to this article***.
Justification	
The amendment ensures that the harmonisation objective of Article 93 applies not only to the initial processing activities carried out in the context of a clinical trial, but also to the further research activities authorised under this Article.	

ANNEX – OTHER AMENDMENTS

In addition to the areas above, DIGITALEUROPE suggests a number of additional amendments to the MDR/IVDR on three main areas: **Rule 11 and Electronic Instructions (eIFU) for Lay Users.**

Rule 11

Annex I B	
EC text	Amendment
'6.3 Rule 11 Software which is intended to generate an output that confers a clinical benefit and is used for diagnosis, treatment, prevention, monitoring, prediction, prognosis, compensation or alleviation of a disease or condition is classified as class I, unless the output is intended for a disease or condition: - in a critical situation with a risk of causing death or an irreversible deterioration of a person's state of health, in which case it is classified as class III; - in a serious situation with a risk of causing a serious deterioration of a person's state of health or a surgical intervention, or to drive clinical management in a critical situation in which cases it is classified as class IIb; - in a non-serious situation, or to drive clinical management in a serious situation or to inform clinical management in a critical or serious situation in which cases it is classified as class IIa.';	***Software which is intended for a medical purpose and generates an output that is used for diagnosis, treatment, prevention, monitoring, prediction, prognosis, compensation or alleviation of a disease or condition is classified as class I, unless its output is intended to address a disease or condition in one of the following situations***: • ***to treat or diagnose in a critical situation, in which case it is class III;*** • ***to treat or diagnose in a serious situation, or to drive clinical management in a critical situation, in which cases it is class IIb;*** • ***to treat or diagnose in a non-serious situation, to drive clinical management in a serious situation or to inform clinical management in a critical situation in which cases it is classified as class IIa.'***
Justification	
The amendment proposed provides for a simplified version of the original Commission's proposal with a few subtle tweaks to further clarify scope of Class I software that better reflect clinical realities providing more legal clarity for manufacturers. The current application of Rule 11 of Regulation has resulted in the systematic up-classification of low-risk medical device software, imposing disproportionate regulatory requirements that are often not commensurate with the risks involved. The lack of clear criteria for Class I software further limits risk-based classification and creates unnecessary barriers to innovation and market access. The proposed amendment welcomes and supports the Commission's objective of simplifying the classification framework for medical device software. By aligning Rule 11 more closely with the International Medical Device Regulators Forum (IMDRF) Software as a Medical Device (SaMD) risk-classification framework, it establishes a clearer and more proportionate risk-based approach, with Class I as the baseline classification and escalation based on the software's intended clinical use and the seriousness of the healthcare situation. This would allow low-risk software that supports healthcare	

delivery, but does not itself determine high-risk diagnostic, treatment or clinical-management decisions, to remain in Class I. At the same time, software intended to diagnose, treat or drive clinical management in serious or critical situations would remain subject to higher classification and appropriate regulatory scrutiny. The amendment therefore preserves patient safety while ensuring that regulatory oversight remains proportionate to risk. The amendment also supports international regulatory convergence by bringing the MDR classification framework closer to internationally recognised IMDRF principles.

Electronic Instructions (eIFU) for Lay Users

Recital 45a (new)	
EC proposal	Amendment
NA	***In order to ensure that users benefit from accessible, understandable and up-to-date information, in line with the digital transformation of healthcare, the provision of instructions for use in electronic form should be facilitated. This should include, where appropriate, use by lay users, subject to conditions ensuring continued patient safety, appropriate access to information and inclusiveness, including the availability of paper instructions upon request where necessary.***
Justification	
Introducing a recital to enable the extension of eIFU to lay users would ensure a more future-proof and proportionate framework, supported by implementing acts defining appropriate safeguards. This would enhance patient safety by ensuring timely access to the most up-to-date information, while supporting the digitalisation of healthcare and increasing patient interaction with digital tools.	
Annex I, Chapter III, point 23.1	
EC proposal	**Amendment**
General requirements regarding the information supplied by the manufacturer Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, taking into account the following:[...]	General requirements regarding the information supplied by the manufacturer Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, ***or, where appropriate, in electronic format*** , taking into account the following:[...]
Annex I, Chapter III, point 23.1(f)	

Instructions for use may be provided to the user in non-paper format (e.g. electronic) to the extent, and only under the conditions, set out in Commission Implementing Regulation (EU) 2021/2226 or in any subsequent implementing rules adopted pursuant to this Regulation.	Instructions for use may be provided to the user in non-paper format (e.g. electronic) ~~to the extent, and only under the conditions, set out in~~ ***ensuring continued patient safety, appropriate access to information and inclusiveness, including the availability of paper instructions upon request where necessary.*** ***The conditions for providing instructions in non-paper format shall be set out in*** Commission Implementing Regulation (EU) 2021/2226 or in any subsequent implementing rules adopted pursuant to this Regulation. ***Any such rules should be updated without undue delay by the Commission pursuant to the revision of this Regulation.***
Justification	
eIFUs support the digital transformation of healthcare and reflect the growing use of digital tools by patients. In addition, digital formats improve accessibility and user experience, including for individuals with visual or cognitive impairments, through adaptable and multilingual content. Furthermore, reducing reliance on paper documentation contributes to environmental sustainability by lowering resource consumption, emissions, and packaging requirements. This approach is consistent with the direction of the MDR/IVDR.	

FOR MORE INFORMATION, PLEASE CONTACT:

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About DIGITALEUROPE

DIGITALEUROPE is the leading trade association representing digitally transforming industries in Europe. We stand for a regulatory environment that enables European businesses and citizens to prosper from digital technologies. We wish Europe to grow, attract and sustain the world's best digital talents and technology companies. Together with our members, we shape the industry policy positions on all relevant legislative matters and contribute to the development and implementation of relevant EU policies. Our

membership represents over 45,000 businesses who operate and invest in Europe. It includes corporations which are global leaders in their field of activity, as well as national trade associations from across Europe.