



Biomedical Alliance in Europe

October 2025

Reply to the call for evidence on the Digital Omnibus (Digital Package on Simplification)

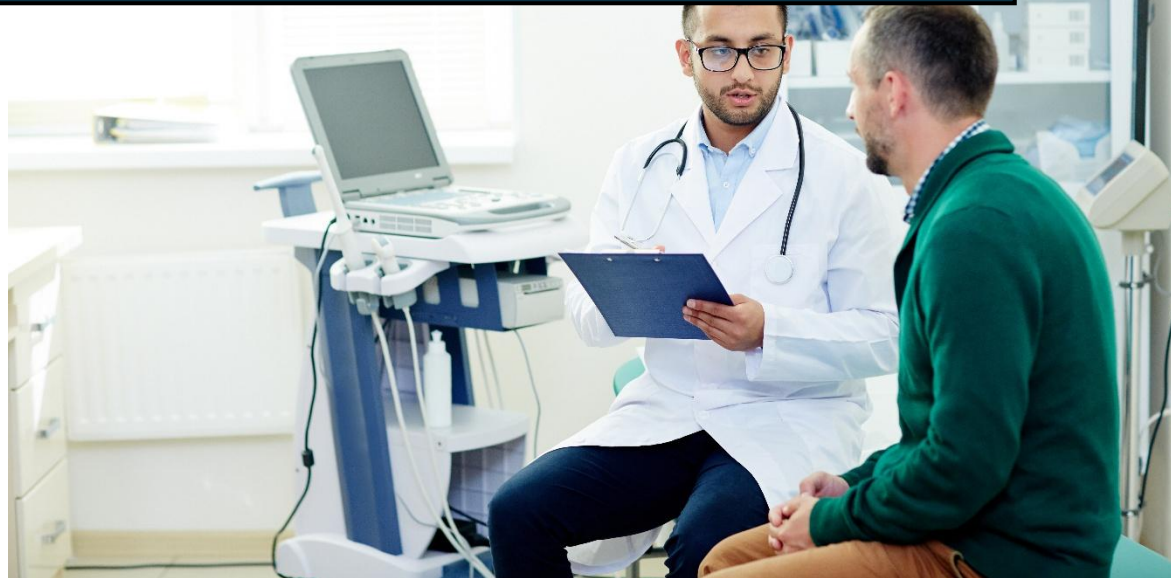




Table of contents

Table of contents	1
1. Introduction	1
2. Regulatory complexity	2
3. Health data	2
4. Artificial Intelligence	2
4.1 AI applications across medical specialities.....	3
4.2 Challenges related to the use of AI in healthcare	3
4.3 Challenges in the implementation of the AI Act	4
5. Conclusion	4

1. Introduction

BioMed Alliance welcomes the European Commission’s intention to simplify digital rules including through the Digital Omnibus Package but urges policy makers to take into account the specific circumstances in different sectors. For instance, in the health sector, digital health, health data sharing, and AI have many potential benefits for advancing healthcare and facilitating healthcare, but the potential risks for patient and public health are substantial. The sector is also governed by numerous overlapping regulatory frameworks, creating uncertainty and increasing the risk of fragmented interpretation or implementation. The 35 European medical and research societies, represented within BioMed Alliance, believe that addressing persisting issues and simplification are essential, while maintaining strong safety standards. At the same time, we believe that more sector-specific guidance for the health and biomedical research sectors is key, considering the unique characteristics of these sectors and their importance to both public health and the economy.

The call for evidence refers to businesses and SMEs as important target groups that will benefit from simplifications, but any decrease in the administrative burden for the for-profit sector should be mirrored in the public and non-profit sector. The backbone of R&D in Europe starts much earlier, in the clinics, hospitals and universities, which are largely publicly funded. So, anything that is deemed ethically acceptable for SMEs, should also allow for less bureaucracy in non-profit research settings. In health research it is healthcare professionals and clinical researchers who have direct contact with patients and citizens and are working to respond to their needs in the most effective and efficient manner. These are often resource constrained settings, where simplification could alleviate some of the burdens that they face.



2. Regulatory complexity

There is a clear need for regulatory clarity on the overlap between frameworks in digital health including the General Data Protection Regulation (GDPR), Data Act, Medical Devices Regulation (MDR), Artificial Intelligence Act (AI Act), and European Health Data Space (EHDS). While EHDS was initially seen as a potential solution for harmonising health data rules and addressing some GDPR challenges, concerns remain about the increasing complexity from overlapping and layered regulations, and the risk of fragmented implementation and interpretation of EHDS at national and regional level. To this day, the GDPR continues to be interpreted differently across countries and health institutions, leading to concrete barriers to health data sharing and health research. Clear guidance is essential for all stakeholders to navigate the complexities and avoid potential conflicts in compliance.

3. Health data

Health data forms the basis for understanding patient needs, and the delivery and improvement of care. In addition, it can advance research contributing to the development and use of AI technologies, new medicines, devices or diagnostics. Maintaining a high level of data quality and standardisation is therefore key, as ‘garbage in is garbage out’. It is therefore essential that policy makers at EU and national level invest in the implementation of EHDS, and work with stakeholders to ensure it responds to the concrete needs in healthcare and research sectors and that it will become a true asset for not only industry involved in the healthcare sector, but also to benefit health of EU citizens. Ethical use is important to ensure trust and integrity of the system.

At the same time, it is essential to involve healthcare professionals and researchers throughout the transition to digital health, to ensure the concrete experience on the ground in the healthcare sector is reflected. Capacity building is also key, as well as ensuring that health data collection and use facilitate the work of healthcare professionals and researchers, while not putting a burden on their already busy schedules. Any simplification must strike the right balance, so it does not introduce extra complexity into the roles and obligations of data holders and users under the EHDS.

4. Artificial Intelligence

Healthcare professionals and researchers are increasingly using artificial intelligence across different medical fields, for instance in diagnostics, radiology, research, clinical trials, generative AI-based solutions for workflow and patient information management. Artificial intelligence has the potential to facilitate patient diagnosis and care, and alleviate administrative burdens, but at the same time it also entails increased risks and burdens. Healthcare professionals are responsible for ensuring the quality of care to their patients and will therefore have increased responsibilities in oversight and validating results generated by AI. There is a need for frameworks that guarantee high data quality, secure exchange, and compatibility between systems, which facilitate a safe use of transparent AI tools that correspond to the demands of clinical practice.



Biomedical Alliance in Europe

The BioMed Alliance has conducted a survey among European medical societies to assess how societies and the healthcare professionals and researchers that they represent use AI, and what sort of challenges they encounter. In total, 15 societies replied, and an overview of the results is provided below.

4.1 AI applications across medical specialities

Medical societies argue that AI already supports diagnostic accuracy, streamlines data interpretation, and enables predictive modelling for patient outcomes. Applications range from imaging and lab analysis to personalised treatment planning and drug development. AI was also cited as playing role in managing complex datasets, improving procedural precision, and enhancing real-time decision support.

4.2 Challenges related to the use of AI in healthcare

Healthcare professionals experience an increasing number of challenges when it comes to the use of AI in health care and research settings. An overview of the challenges shared in the survey is provided below.

Transparency and trust: lack of transparency in AI-decision making; loss of patient trust; fear of misuse of personal health information

Validation, reliability and bias: lack of robust validation of AI algorithms; risk overfitting due to uncontrolled or skewed sources; worse performance of diagnostic tools on underrepresented populations; lack of diversity and representativeness in training data; need for evidence-based research to assess effectiveness;

Data quality and standardisation: poor data quality, scarcity, heterogeneity; non-standardization of lab tests; limited access to representative and usable datasets; need for interpretable models and understanding of causal relationships)

Human-AI interaction and clinical responsibility: ethical concerns around automation and decision-making; balancing AI support with clinical oversight (leading to additional responsibilities for healthcare professionals), risk that patients over-rely on AI systems bypassing quality control provided by clinicians, need for training of healthcare professionals

AI regulation and policy: privacy risks and data protection gaps; rapid tech evolution outpacing legislation; need for clear and enforceable AI regulations that are future-proof, cost and capacity barriers for smaller actors, need for support for training and capacity building



4.3 Challenges in the implementation of the AI Act

Europe has been ambitious in creating an AI act, but now it is essential that issues are addressed in the implementation. Considering the unique role of AI in the health sector, the potential risks and benefits for patient care, and the fact that most AI tools used in the healthcare sector are considered to be high risk systems under the AI Act, sector-specific guidance is key. Regulatory ambiguity needs to be resolved, liability frameworks and the roles and responsibilities of healthcare professionals need to be clarified, and stakeholders must be consulted in all stages of the implementation of the AI Act. Below is an overview of some of the key issues that medical societies mentioned in their replies to the BioMed Alliance Survey.

Regulatory complexity and gaps

- Lack of specificity in the AI Act regarding healthcare applications; overlap with existing EU legislation (MDR, IVDR, GDPR); complexity in defining and categorizing AI systems; uncertainty around compliance verification and institutional adherence

GDPR and data access barriers

- GDPR restricts access to data needed for training algorithms; data protection rules limit real-time surveillance and innovation (e.g. agentic workflows); non-standardised medical test results risk flawed AI output

Human-AI role definition

- Need to balance AI's role with medical practice boundaries, lack of clarity on clinician and patient involvement as co-developers, more guidance needed on the roles and responsibilities of healthcare professionals (including in providing human oversight)

Institutional readiness and transparency

- Limited resources and capabilities in hospitals and relevant organisations; need for transparency and public understanding of AI systems, need for training & capacity building of healthcare professionals

Global competitiveness

- Europe's disadvantage compared to China and the United States; AI development outpacing regulation, risking innovation lag

5. Conclusion

The Digital Omnibus proposal can provide an opportunity for simplification, but it is essential that it takes a balanced approach considering key challenges in the healthcare sector. The proposal provides an opportunity to alleviate some of the burdens placed on both business and the not-for-profit and academic sectors. However, any reform must be forward-looking, uphold robust safety standards, and be developed in close collaboration with stakeholders, particularly



Biomedical Alliance in Europe

healthcare professionals, patients and (academic) researchers who are at the forefront of research and care. Sector-specific guidance, regulatory clarity, and investment in capacity building will be key to ensuring that digital transformation supports (instead of hinders) healthcare professionals and researchers, so that Europe will indeed be at the forefront of digital health and AI Innovation.