



Biomedical Alliance in Europe

BioMed Alliance response to the public consultation on the European Health Data Space

On 26 July 2021 the Biomedical Alliance submitted a response to the public consultation on the European Health Data Space (EHDS) launched by the European Commission.

The EHDS can be a promising tool in facilitating health data exchange and contributing to better care and health research, if it is implemented properly. It must follow a balanced approach, protecting privacy and ensuring patient trust in the system on the one hand while ensuring easy and appropriate access to data among healthcare workers and researchers on the other. A balanced approach between ensuring privacy and facilitating access to data is necessary.

The EHDS should aim for a legislation embedding the multitude of health data usage and should help in reducing regulatory complexity. The proposal differentiates between different categories of primary and different types of secondary data, while the division is more blurred and a concrete separation between primary use and secondary use of health data cannot be strictly upheld.

The European Health Data Space should interlink with other efforts in the digitalisation of health and health data sharing, but it needs a strong basis in line with the existing framework and other legal initiatives, otherwise it might result in further complicating the European health research landscape. The EHDS should not overlap with other existing legal initiatives but rather clarify the gaps between these initiatives and bring legal clarity and certainty with respect to its own remit.

The EHDS should contribute to the creation of strong legal basis with criteria for processing personal data managed in scope of clinical research and secondary use of data along with clear set of rules regarding storage, access and sharing of data, as well as for personal data transfers and anonymisation of data.

Finally, the EHDS should pave the way towards a harmonised and coordinated system across member states to avoid duplications and promote interoperability and access.

BioMed Alliance members are ready to continue the discussions on the digitalisation of healthcare, the use and exchange of data in research and establish a EHDS that can truly benefit European health.

About BioMed Alliance

The Biomedical Alliance in Europe is the result of a unique initiative of 36 leading European medical & research societies that together include more than 400,000 researchers and health professionals. It is a not-for-profit organisation committed to promoting excellence and innovation in the European healthcare field with the goal of improving the health and well-being of all European citizens.

Its members are important players in the field of biomedical research and digital health, and actively contribute to the responsible sharing of health data e.g. through the organisation of registries, health research projects and educational activities.