The Biomedical Alliance in Europe (BioMed Alliance) very much welcomes the initiative to establish a European Health Data Space (EHDS), as we believe it can play an important role in facilitating health data sharing to improve the health of European citizens.

The 35 medical societies that together shape the BioMed Alliance aim to contribute to this mission in multiple ways, as they engage in health research, provide information and education to healthcare professionals and strive to improve European healthcare in general. They directly contribute to health data sharing, for example by being involved in data-driven research projects and setting up databases and patient registries. They believe the European Health Data Space could play an important role in facilitating health data exchange, which can benefit biomedical research and allow healthcare workers to take better informed decisions regarding patient care.

In order to ensure the new European Health Data Space becomes a success and will play an impactful role in the European health system, it must be 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.

**Benefitting patients, healthcare professionals and researchers**

Health data is complex; it is dynamic as it evolves rapidly and includes a variety of multidisciplinary information. The EHDS should embrace this complexity and take an inclusive approach by ensuring the incorporation of a broad range of patient groups and disease areas. It should take a patient-centric vision and clearly identify objectives and challenges.

The BioMed Alliance believes that the EHDS could help remove barriers for evaluating (pseudonymised) data that is collected in a variety of healthcare activities for its use in health research. It should integrate existing initiatives and data sources, and data gathered in clinical studies and patient registers, including joint analyses from different sources. Eventually, the EHDS could provide the necessary data supporting the entire process from basic research, to the development of new health innovations, patient treatment and follow-up.

It should interlink with other efforts in the digitalisation of health and health data sharing and focus on addressing obstacles to the interoperability of IT infrastructure in the healthcare sector. The
EHDS could for instance play a role in promoting the harmonisation of electronic health data formats in the EU e.g. by incentivising the uptake of the Commission Recommendation on a European Electronic Health Record exchange format. Increased harmonisation of health records could allow patients to easily and safely export and read their data and make it available to treating physicians anywhere in the EU and eventually even benefit biomedical research.

**Transparency, stakeholder’s involvement and information provision**

The new EHDS needs to be established on a strong foundation of trust. All actors must feel confident in being part of the EHDS, citizens will need to be adequately informed of all pros and cons and health professionals must receive adequate training to effectively and safely make use of the EHDS.

This requires a transparent approach, and information on the EHDS provided to stakeholders such as patients, healthcare professionals and researchers needs to be clear and concise. The involvement of a broad range of stakeholders should be actively sought throughout the preparation and implementation process of the EHDS and beyond. It is essential that its process focusses on enhancing understanding of the necessary complicated technical issues among citizens (including patients), healthcare professionals, researchers and medical societies.

It is also important that the data is of high quality, up to date and usable for health research and treatment decisions so that researchers and healthcare workers are able to make full use of the system. Trustworthy data processing depends on a number of elements, such as good communication, motivation for data sharing, impact of the results of data usage on improvement of patient outcomes, reducing harm, improving health systems efficiency and reducing cost.

In short, the EHDS needs to create space for a broad conversation about the use of health data and what it means for European society in order to co-create a trustworthy environment.

**Harmonising GDPR**

The General Data Protection Regulation has played an important role in enhancing the data protection and privacy of European citizens, but its implementation has had unintended implications that led to barriers to health research and patient care. We outlined some of these challenges in a statement in 2019.

It is vital that the sharing, access and use of health data is facilitated for research and patient care purposes. Diverging application and interpretation of the GDPR among different actors has created barriers to the sharing of health data, and a uniform and balanced application across the EU is necessary. This depends on providing sufficient guidance and legal clarity, and we thus believe the work of the TEHDAS Joint Action led by SITRA is essential for the success of the European Health Data Space. We also believe that a code of conduct for use of personal data in health research will be a promising tool for a greater harmonisation of approaches across the EU. This code must be

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1 [BioMed_Alliance_statement_on_Data_protection_Regulation_-_final.pdf (biomedeurope.org)](bioimedeurope.org)
driven by key stakeholders and designed with and for researchers to ensure it takes into account the full complexity of data sharing in health research.

The Commission will need to find an appropriate response at EU level; one that gives sufficient legal clarity across all EU member states, rather than an additional EU layer of administration on top of the diverse country level responses.

Generating the necessary skills

Continuing Professional Development (CPD) throughout the career of healthcare professionals ensures their knowledge and skillsets remain up to date. CPD activities could help familiarise health professionals with technological developments, and ensure they have the necessary skills to actively contribute to, and make use of, the EHDS.

The European Commission’s Digital Education Action Plan foresees investments for boosting digital literacy across Europe. The EHDS will need to channel resources and investments from the broader programmes (Digital Europe, Horizon Europe, Health4EU etc) to enhance digital skills for healthcare professionals, not only for advanced digital skills, but also for general digital literacy. For example, AI is more likely to be ethically and safely deployed if used by clinicians and citizens who are aware of the opportunities and limitations of data driven tools.

Medical and research societies are important players in Continuing Medical Education and Continuing Professional Development; they organise a range of informative and educational activities including congresses, courses, e-learning and webinars and publish different materials including scientific journals. Members of the Biomed Alliance can therefore play a role in communication to our broad networks of healthcare professionals and researchers across all EU member states. We can also partner with institutions and deliver capacity building through our scientific content and education activities but support and resources will be necessary to implement such awareness raising.

Next steps

The BioMed Alliance believes that the European Health Data Space could facilitate health data sharing in the EU, generating numerous benefits for health research, health care and ultimately citizens. We do believe that careful planning, a broad discussion and appropriate involvement of all stakeholders are necessary to make it a success.

As key actors in the healthcare sector, medical and research societies look forward to continuing the discussion on the digitalisation of healthcare, the use and exchange of data in research and the overall development of the European Health Data Space. We are happy to provide input and support the Commission where necessary through our many activities and contacts with large networks of healthcare workers and researchers.
About BioMed Alliance

The Biomedical Alliance in Europe is the result of a unique initiative of 35 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.