Forum Health Region Baden-Württemberg

THE DIGITAL FUTURE OF MEDICINE:

A position paper prepared by the Forum Health Region Baden-Württemberg on the Proposal for a Regulation on a European Health Data Space

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The digitalisation of healthcare, along with the digital collection and use of health data, open up significant opportunities for medical progress. In the same vein, in healthcare, access to high-quality digital health data has become an increasingly important determinant factor for pharmaceutical, medical technology and biotech industries when deciding where to locate their operations. The protection of individuals and the well-being of patients must be central factors in the digital use of health data. In medicine, as in other fields, it is vital to strengthen our European concepts of data security, data protection and cyber security when competing globally, transforming them into a model for success.

The state of Baden-Württemberg, one of the most eminent healthcare centres in Europe, set up the Forum Health Region Baden-Württemberg in 2018 as a platform for action and innovation in the areas of research, care and industry. The aim was to address the structural issues of the healthcare sector, such as the use of health data, in a crosssectoral manner. The forum adopted the Roadmap Health Data Use Baden-Württemberg containing ambitious measures in March 2022. It is committed to advancing the use of health data for digital medicine also at EU level.

The Forum Health Region Baden-Württemberg welcomes the proposed regulation for a European Health Data Space (EHDS-R) as a significant step for the further development of medicine. Interconnecting large amounts of high-quality data across Europe has the potential to deliver a quantum leap for healthcare provision and health data research, and to foster the development of data-driven medical innovations. The European Health Data Space, potentially encompassing around 450 million citizens, has the potential to lift one of the world's largest interconnected data treasures.

The Forum Health Region Baden-Württemberg recommends that the European institutions pay special attention to the following points going forward:

1. **Harmonising data protection regulations**
2. **Protecting health data in line with cyber security standards**
3. **Healthcare data interconnectivity and standardisation**
4. **Secondary use of health data in the interest of the public good**
5. **Digital literacy among healthcare professionals and digital health literacy among citizens**
6. **Working towards improved data use at all levels**

1. HARMONISING DATA PROTECTION REGULATIONS

Major hurdles for the development of medical research projects are presently presented by nationally and regionally divergent requirements. This, combined with diverse interpretations of the General Data Protection Regulation (GDPR) by a multitude of authorities leads to significant obstacles in research cooperation and in developing new digital products and services across regional and national borders.

- **The Forum Health Region Baden-Württemberg advocates the further harmonisation of legal requirements surrounding data protection** as laid out in the European Health Data Space Regulation (EHDS-R) and thus expects a more standardised interpretation thereof with regard to the use of health data, especially in light of the General Data Protection Regulation (GDPR).

- The EHDS-R should thoroughly take into account the lessons identified in its explanatory statement concerning the partially GDPR related fragmentation and legal uncertainties for medical research in the EU. The regulation must accordingly **contain clear definitions and stipulations regarding its future standardised application.**

- This applies in particular to the **terms "anonymisation" and "pseudonymisation".** Clear European regulations are needed for the processing of pseudonymised data according to strictly controlled technical and organisational specifications. Specifications on technical, organisational and legal measures must be established to ensure sufficient protection against re-identification in order to minimise traceability risks.

- It should be examined to what extent the use of "Confidential Computing" and "Privacy Preserving Technologies" in the secondary use of health data will dispense with end-to-end encryption and the methodology of anonymisation and pseudonymisation.

- Some of the terms contained in the Regulation need further clarification. For example the terms "data owner" and "goods and services that contravene public order or morality".

- The relationship between the GDPR and the EHDS-R needs to be made clear. There is also a need to harmonise the terminology of the EHDS-R, the GDPR and other regulations, such as the term "health data".

2. PROTECTING HEALTH DATA IN LINE WITH CYBER SECURITY STANDARDS

Essential to a European health data space is the protection of the digital provision and use of data according to state-of-the-art or appropriate IT and cyber security standards, such as the ISO/IEC 27000 series. Relevant Member State standards must be taken into account as well.

3. HEALTHCARE DATA INTERCONNECTIVITY AND STANDARDISATION

A prerequisite for harnessing the potential of a European healthcare data pool for medical research and care is that healthcare data be structured and defined in a standardised way across sectors and borders. Increased efforts must also be made to ensure high data quality in order to derive the greatest possible benefit.

Currently, formats and standards for key data sets such as laboratory results, image data or electronic patient records vary not only between Member States but also between different sectors of the health sector.

- The Forum Health Region Baden-Württemberg is pleased that the **EHDS-R intends to establish the urgently needed standardisation of data sets as well as the interoperability of systems and applications for the exchange of data in the EU.** The benefits for patients in cross-border care as well as for medical research and policy-making geared to the future needs of society and for the prevention and acute combating of pandemics are enormous

- The Forum Health Region Baden-Württemberg is working to ensure that **international technology standards are taken into account in the further development of the EHDS-R and that uniform standards are set for data formats along with common definitions of interfaces.**

4. SECONDARY USE OF HEALTH DATA IN THE INTEREST OF THE PUBLIC GOOD

The ability to collect large amounts of data and to link different data sets across sectors with common standards can significantly advance Big Data analytics, AI applications and Personalised Medicine, positively contributing to the safety, quality and cost-effectiveness of medical care. The hitherto fragmented access to health data for research purposes that has been organised at Member State level, sometimes involving a multitude of different authorities, combined with the non-uniform processes for applying for access to health data, represent a major obstacle to medical research. Similarly, access for research-based companies is regulated very differently in each Member State.

- **The Forum Health Region Baden-Württemberg advocates the expansion of EU-wide capacity for secondary use of health data under the umbrella of the HealthData@EU infrastructure. It also favours the simplification of application processes as a deciding factor for the location of research and industry.** The bureaucratic burden of using data for medical research must be reduced.

- **The Forum Health Region Baden-Württemberg is in favour of the EHDS conditioning access for secondary use of health data to the sole purpose of use for such access. In particular, the Forum Health Region Baden-Württemberg welcomes the systematic opening of secondary use of health data for research-based companies serving the public good. In this context, the definition of the term "public good" will be of particular importance.** The industrial healthcare sector, which is very strong in Baden-Württemberg in particular, contributes significantly to medical progress and the improvement of care. The same applies to healthcare providers who compile treatment data for secondary research use and to the health insurance funds who conduct health service research to improve care for the insured.

- **The permitted purposes of data use, prohibitions on data processing, and transparency provisions must also be clearly defined and developed.** A thorough definition of permitted uses, such as the design of health

care contracts with the aim of improving care for the insured, and unpermitted uses, such as unauthorised access to data for advertising, drafting of insurance contracts, or for disclosure to employers is required.

- **The starting point for the admissible purposes of data use must be patient welfare and the right to privacy.** Patients must be able to object to the transfer of their data. An opt-out option must therefore be included in the regulation.

- The fiction of being able to authorise data release for the secondary use of electronic health data after the expiry of the deadline mentioned in Art. 46 of the EHDS-R must be abolished with regard to the application requirements to be examined by the access point. Prioritisation of the processing of requests for data use according to the purpose of access should be considered.

- **Establishing trust models can help build trust and serve as part of the protection concept.**

- Penalties for improper use provided for so far should not be limited to access restrictions in cases of misuse. Further sanctions should rather be uniformly regulated, for instance profit skimming and/or professional bans could be applied.

5. DIGITAL LITERACY AMONG HEALTHCARE PROFESSIONALS AND DIGITAL HEALTH LITERACY AMONG CITIZENS

Digitisation in health care and the expanded possibilities for using health data for research must go hand in hand with empowering citizens to use digital services and infrastructures in order to make informed choices. Only then will the expansion of digital health services and the wider use of patient data for the common good be accepted, only then will digital tools be widely used. The same applies to health and care professionals who have to prescribe and communicate digital health services in a competent and professional manner. Precisely against the backdrop of the planned expansion of secondary use of health data: educating citizens about processes and on how best to exercise their rights is essential to ensure informative self-determination.

- **The Forum Health Region Baden-Württemberg advocates adding the dimension of promoting digital health literacy among citizens to the EHDS-R.**

- Another decisive factor in ensuring that citizens receive competent medical and nursing care and information in a world of digital health is that **digital competence be structurally anchored within higher education as well as in the initial, further, and ongoing training of medical and nursing staff.** Employees must be trained in digital tool use, in their methods and their application. This must be done in accordance with new knowledge and technology realities.

- The EHDS-R should therefore **be underpinned by a strategy that strengthens the digital health literacy of citizens in Member States and develops digital literacy among healthcare professionals.** Trust institutions such as certified data trustees can provide support here. Existing European guidelines and instruments such as the Declaration on European Digital Rights and Principles or the Digital Education Action Plan should be included.

6. WORKING TOWARDS IMPROVED DATA USE AT ALL LEVELS

The development of EU-wide uniform standards for primary and secondary use of health data for research and development by 2025 is a very ambitious project with immense potential that will enable a significantly greater wealth of data to be used throughout Europe - both for the benefit of patients and for innovation. Digitisation and digital medicine develop very differently across Member States. It is therefore all the more important that Member States prepare for the EHDS and take action now to upgrade their infrastructure and promote harmonisation of standards and infrastructure, as well as networking across sectors. All new measures must now anticipate the forthcoming EHDS. In the further course of action, it is important to set ambitious and realistic deadlines. Baden-Württemberg has therefore provided key points for the design of the German Health Data Usage Act planned for 2023 and is lobbying the federal government for the speedy submission of a draft proposal.

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