POSITION PAPER

to support the implementation of the European Health Data Space (EHDS) in Germany

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1. Deficits in the implementation of the EHDS in Germany endanger the research location

In the European Union, billions of data sets exist that have been collected in the context of medical care or for other purposes, but are currently largely unused. Health systems such as those in Finland, Iceland or Israel have proven that the use of these data for research purposes can make a significant contribution to improving the quality of care and developing innovative procedures and products. The European Health Data Space (EHDS) addresses this challenge by increasing the interoperability of national health systems, thereby enabling patients to access and manage their health data across the EU. At the same time, it opens up the possibility of using the existing data for research purposes via data access bodies.

However, there is a threat of restrictions in the current EU legislative process and the national implementation that may jeopardise the goals that have been set. In particular, there is a risk that the data basis will be insufficient, that the national data access bodies will be inadequately equipped and that private-sector research projects will be disadvantaged compared to public-sector projects. The restrictive data protection provisions of German state and social law could additionally put Germany at a further international disadvantage in research.

In the EHDS Coalition initiated by Dierks+Company, representatives of companies and associations with focus on research or data processing as well as patient organisations have therefore joined forces to advocate for a successful implementation of the EHDS and non-discriminatory access to the EHDS for private and public research projects.

2. Optimal data basis and non-discriminatory use

The planned secondary use of electronic health data aims, among other things, to develop new and improved therapies more quickly from data provided in a structured manner in order to improve health care for all. The EHDS can only develop its potential and realise its intended goals if as much as possible of the data already collected can be used. Therefore, the full interoperability of health data available in the EU and the widest possible availability for data use purposes are indispensable prerequisites for the functioning of this undertaking. For this to succeed, all stakeholders – the population, the care systems, the private sector companies, and the public institutions – must work together. Everyone must make their contribution to the success of the whole. For this reason, we need a paradigm and attitude shift regarding the permission to access and use health data.

With Chapter IV of the Draft EHDS Regulation, the European legislator creates the legal basis required under data protection law for processing anonymised health data for secondary purposes based on a statutory permission. Other initiatives point in the same direction: The digitisation strategy of the Federal Ministry of Health (BMG) and the Health Data Use Act (Gesundheitsdatennutzungsgesetz, GDNG) are also aimed at making the large amount of existing health data usable for purposes of the common good in the future.

To achieve these purposes, the BMG's digitisation strategy explicitly provides for secure data access for public and private research. In the national shaping of the EHDS, equal access for private research must not be relativised. According to the amended draft of the EU Parliament of 10 February 2023, Article 34(1)(e) of the draft EHDS Regulation shows even more clearly the intended equality of private and public research – by clarifying that development and innovation as well as training of products also fall under the concept of research as defined in the EHDS Regulation.

With the Draft EHDS Regulation, the EU Commission has clearly formulated the goal of harmonising the use of electronic health data throughout Europe. In order to achieve comprehensive implementation and acceptance of the EHDS in Germany as well, Germany must embrace this understanding and position itself as a role model for Europe and as a shaper of the EHDS.

3. What is important for shaping of the EHDS in Germany and Europe

The EHDS Coalition is convinced that the EHDS can strengthen Europe as a research location. However, the Draft EHDS Regulation still leaves many details open, which triggers the need for clarification. The EHDS Coalition believes that the European legislator and the Commission have a duty to create clarity for the stakeholders in a timely manner with regard to the definition of "electronic health data", the requirements for the electronic health record systems and the standards required in the EHDS.

Even though the basic rules are laid down by the Draft EHDS Regulation, the Member States are also given leeway in designing the processes for implementing the EHDS. This results in levers that are decisive for the success or failure of the EHDS. In connection with the successful secondary use of data, the EHDS Coalition sees strong potential for the success of the EHDS in the following points in particular – and at the same time the risk that the EHDS will not be filled with life in the case of country-specific or incomplete implementation.

3.1 Only a broad, qualified database leads to success

The EHDS can only develop its full potential if a comprehensive and broad data basis is created for research. The original approach of the draft to create a legal basis for the use of anonymised data (in exceptional cases pseudonymised data) on the basis of a statutory permission is therefore the preferred way, as such a database can be expected to be comprehensive and complete.

The EU Parliament also clarifies in the revised draft in Article 33(5) of the Draft EHDS Regulation that the consent of the data subjects is not required for the use of data in the context of secondary use under the EHDS Regulation. Also, from the point of view of the EHDS Coalition, weighing the interests goes in favour of the common good, which outweighs the interest of individuals in not having their data processed for secondary purposes. The interests of the data subjects are sufficiently protected since generally only anonymised data shall be processed for the purposes envisaged by the EHDS and adhering to security standards is required. The EHDS Coalition considers all data holders to be under

an obligation to accept the use of anonymised health data to establish a foundation for the common good, especially since anonymous data is not subject to data protection anyway. An opt-out would significantly counteract the objective of this duty to the common good.

The new version of Article 33(5) of the Draft EHDS Regulation now provides that access bodies should provide for an '*accessible and easily understandable opt-out mechanism*' by which natural persons can express their '*wish not to have all or part of their personal electronic health data processed for some or all secondary use purposes'*. If the establishment of such an opt-out – as also envisaged in the digitalisation strategy of the Federal Ministry of Health – cannot be avoided and is conducive to the acceptance of the EHDS, it should only be possible through the data subjects' own initiative. At the same time, it should be ensured that the right of objection does not entail overly complex requirements and does not discriminate against certain economic sectors or disadvantage private-sector research. The European and German legislators should evaluate in short intervals whether it is possible to ensure that the use of data is sufficiently functional even under conditions of objection.

- *It is crucial for the success of the EHDS that the implementation – following the principle of solidarity – enables the use of health data on the statutory basis even without the right to object.*
- *Should an objection mechanism nevertheless be set up, it must be based on an individual decision, it must not become automatic.*
- *When setting up the objection mechanism, care must be taken to ensure that it is trustworthy and not too granular. In particular, an objection based on data user categories should be avoided.*

3.2 Establishment of a functional, trustworthy data access in Germany

The possibilities for secondary use of health data in the EHDS depend on the functioning of the access bodies to be set up by the Member States. They are to process requests for use, pseudonymise or anonymise data, set up secure processing environments for the provision of the data, ensure transparency vis-à-vis natural persons and handle their objections. For the implementation in Germany, a few ways are possible:

Centrality: Based on Article 74(1) No. 13 of the *Grundgesetz*, the establishment of a central federal access point is conceivable. This would have the advantage that the information required for the efficient fulfilment of tasks would be available in one place and no additional coordination between individual state authorities would be necessary. Without such centralisation, the EHDS Coalition believes that there is a risk that complicated rules of jurisdiction and procedure for data holders, data users and data subjects will hinder the success of the EHDS.

Decentralisation: On the other hand, the establishment of several access bodies could promote competition between the individual data access bodies for service-oriented and effective procedures as well as modern usage environments. 'Hybrid solutions' are also conceivable, in which there are

several access bodies, but they access common databases and use one infrastructure to fulfil their tasks. In this context, it would make sense to set up a joint institution/conference for regular coordination, whereby this should act in a more binding manner than, for example, the data protection conference (*Datenschutzkonferenz)* of the states.

Anonymisation or pseudonymisation are necessary before provision by the access point close to the data holder in order to guarantee the data subjects' right to informational self-determination. The bodies responsible for this (trustees) should be installed as separated institutions from the access body and also have a secure concept for decentralised data rooms for data holders.

Such a concept for national access bodies could serve as a blueprint for other European states.

The EHDS Coalition therefore considers it necessary that the following framework conditions are met:

- *In order for the key position of data access body to be filled effectively in Germany, application, provision and access processes must be designed in a uniformly simple and efficient manner throughout the country in order to keep the administrative burden low and to approve data access for research quickly and within defined timeframes.*
- *The access body/bodies must be adequately funded, staffed, and technically equipped from the outset.*
- *The function of anonymisation or pseudonymisation should be performed by institutions that are separate from the access body and close to the data holder, in order to strengthen public trust in the access body/bodies and the EHDS, and, ensure a concept also for decentralised data rooms.*

3.3 Involvement of companies in the health economy as valuable data holders

The draft EHDS Regulation provides for data holders to make electronic health data available for secondary use. Data holders are organisations or researchers in the health or care sector who have the right or obligation or are technically capable of making certain data available. The EHDS Regulation is intended to oblige not only treatment facilities, but also and in particular private industry to contribute the electronic health data they hold for the privileged purposes of secondary use, e.g. data generated by the use of medical devices or data from clinical trials. Already today, industry is a significant data provider and enables access to e.g., clinical trial data in accordance with the Clinical Trials Regulation. In order to make the EHDS a success and to make its contribution to the common good, the EHDS Coalition is expressly in favour of conducting a national dialogue with the politically and professionally responsible stakeholders on which (further) data on the part of industry can be usefully and meaningfully contributed to the EHDS. It is imperative to integrate representatives of affected data holders in order to find solutions that are suitable for everyday use in a cooperative and consensus-based manner.

However, the EHDS Coalition is explicitly critical of Article 33(4) of the draft EHDS Regulation, according to which data containing protected intellectual property and trade secrets should be made available even if '*all measures necessary to preserve the confidentiality of IP rights and trade secrets'* are taken. Protected intellectual property should in principle only have to be shared on a voluntary basis. For IP rights and trade secret holders, there is a need for much more clarity on what information must be shared in light of this regulation, how this information can actually be protected, for example, through data sharing agreements, which should also include provisions for the protection of the data holder, and under what conditions the provision can also be refused.

- *In order to maintain competition and the commitment of private stakeholders to develop innovations in Germany and the EU, intellectual property must be protected. Legislators must provide clarity as to which data must be made available and in what form, and under what conditions provision can be refused.*

3.4 Equal participation of companies as data users

In order to be able to make their contribution to the success of the EHDS and for the common good as data users, the private sector must be equal data users on an equal footing. Only in this way can the potential of the data available in the EHDS be fully exploited for improvements in health care.

In this context, the EHDS Coalition is particularly critical of the provision introduced by the EU Parliament in Article 45(2)(fa) of the draft EHDS Regulation, according to which the request for data use should also include a '*description of how the data applicant is qualified vis-à-vis the intended purposes of data use, such as professional qualifications to demonstrate appropriate expertise*'. The EHDS Coalition sees the danger of indirect discrimination against industry and private research in this requirement.

- *As envisaged by the draft EHDS Regulation, only the secondary purpose of use may determine whether an applicant may use data or not.*
- *It must be ensured that professional qualifications in the private sector are also sufficient as proof of the expertise required for the purpose pursued.*

3.5 Creation of a fair fee policy

Data holders are entitled under Article 42 of the Draft EHDS Regulation to receive fees from data users for providing the data. These fees are to be '*transparent*' and '*proportionate to the costs of collecting and making […] available*' the data, as well as '*objectively justified*' and shall not restrict competition. If data holders and data users do not agree on a fee, the access body can set the fee. According to the draft EHDS regulation, fees are also to be reduced under certain conditions, e.g. due to the importance of the research to the society. The EU Commission can issue implementing acts on the fee policies and structure.

Data holders already incur expenses outside of business operations with regard to the numerous new obligations under the Draft EHDS Regulation (such as the reporting and provision of data under Article 41 of the Draft EHDS Regulation) or also for meeting the requirements for the data quality and utility label (Article 56 of the Draft EHDS Regulation). Other expenses may be added. When determining a fee structure, the expenses incurred by the data holders prior to provision must be taken into account as well as those incurred through the provision itself.

With regard to private-sector data holders who generate, curate and process data through their own efforts and thus make it usable for further research, the EHDS Coalition sees the risk that a disproportionate fee structure will drive such private-sector data holders out of the European market. Fees for the use of these data should therefore remain freely negotiable.

- *The reduction of fees based on the 'importance of research to the society' must not lead to a two-class system in fee policy. It must be defined or classified when a research project is important to society. Low fees must not lead to low-value research requests.*
- *The effort required to report and provide data and to fulfil the requirements for the quality and benefit label should be taken into account in the fee structure.*
- *The provision of data by companies whose business purpose is to collect data must not be undermined by state-set fees for the use of this data. For these companies, a fee structure should not be regulated but left to the free market.*

3.6 Connection of small medical practices as voluntary data holders

The EU legislator has exempted micro-enterprises from the obligation to provide data in Article 33(2) of the Draft EHDS Regulation in order not to put administrative burdens associated with reporting and providing data on service providers with fewer resources. At the same time, the definition of data holder under Article 2(2)(y) of the draft EHDS Regulation provides for the possibility that data holders may also be entitled or obliged to provide data by Member State law. In order to use the potentials of the EHDS and to prevent data bias, all stakeholders involved in the healthcare system should be involved in the EHDS. Since the data of smaller health care providers are also important for research questions – especially in the context of health care research – and the non-inclusion of such data can lead to a distortion and bias of the data situation, a legal basis for the voluntary provision of data should also be created for micro-enterprises, e.g. smaller medical practices. With the introduction of automated solutions, these could also be supported administratively. A solution via the electronic patient file (*Elektronische Patientenakte, ePA*) within the framework of the telematics infrastructure would be conceivable here. The EHDS Coalition considers a regular review of the voluntary solution and, if necessary, an obligatory provision for micro-enterprises to be introduced at a later date to be sensible.

- *A statutory basis according to data protection law should be created for the provision of data in the EHDS for micro-enterprises and simple solutions for a speedy connection process should be developed.*

3.7 Use of data for teaching purposes

In addition to research and other secondary purposes, the original draft of the EHDS Regulation also stipulated that electronic health data may be used for '*education or teaching activities in health or care sectors'*. In the new version of the EU Parliament, only '*university and post-university teaching activities in health or care sectors*' are allowed. This raises the crucial question of whether electronic health data may not be used in the context of non-university education after all. In view of the lack of skilled workers and the strengthening of nursing professions, the improvement of education should also be achieved with the help of better data.

- *The German legislator should create a legal basis that also allows the secondary use of health data for educational purposes in non-university professions.*

3.8 Early information and awareness-raising among the public

In order for the EHDS to realise the goals it has set itself and the desired success, primary and secondary use must be thought of together from the beginning and implemented together. At the same time, acceptance should be created in the population at an early stage through transparency, because the provision of data for secondary use without consent is laid down in German law (compare e.g. Section 27 of the Federal Data Protection Act), but is not yet widespread in practice. The digitisation strategy initiated by the Federal Ministry of Health follows a similar approach and can contribute to the acceptance of this idea. The potential of the EHDS in terms of secondary use for the common good must be made transparent to the public in order to counteract a burgeoning critical mood at an early stage.

- *Politicians and the executive should start communicating at an early stage about the EHDS and its benefits for the general public and individuals in order to create transparency about the project and thus strengthen acceptance among the population.*

4. The EHDS Coalition is available for further dialogue

With the EHDS, we now have the opportunity, both nationally and EU-wide, to make access to and use of health data so comprehensive for the first time that health care for all can be raised to a completely new and tangibly positive level in the future. We must not miss this historically great opportunity – even if there is still a need for discussion on the details. The EHDS Coalition is ready for constructive exchange.

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