



## Biomedical Alliance in Europe

EHDS Consultation response 26 July 2022

# Creating an EHDS that maximally contributes to clinical care and research

The European Health Data Space could have a transformative effect on the healthcare and research sectors by facilitating health data sharing and use for primary and secondary purposes. The BioMed Alliance, an organisation representing 36 medical societies, welcomes the intention to reduce barriers to data sharing and to ensure that patients, healthcare professionals and researchers have better access to data.

We believe that the following aspects should be considered in discussions in the context of the legislative procedure on the proposal for the regulation for the European Health Data Space, its implementation and operation:

### Health data sharing for primary use

Ensure synergies between EHDS for primary and secondary health data sharing.

- The primary and secondary uses of data are often closely connected in health and their scope is defined by different authorities in different ways. Patients participate in clinical trials or health research, and healthcare professionals wear multiple hats and take on roles in health research, clinical trials, patient treatment, and sometimes even clinical assessment for regulatory and policy purposes.
- The line between the primary and the secondary use of electronic health data in a research study such as a clinical trial is thus already blurred and the EHDS regulation uses the same terminology when labelling the electronic health data managed by the hospital or the patient him/herself. A clarification of the interplay of the EHDS definitions of these terms and the currently existing legal framework in the clinical research field would be of high importance.
- EHDS for primary and secondary use should have consistent application and appropriate feedback loops. We also need quality primary data for it to be usable for secondary use, as the two are connected and this must be reflected in the legislation.

EHDS should facilitate the work of healthcare professionals, and not lead to additional workload while they are already overburdened by a rising number of tasks.

- Accessing and processing the data, understanding the system and informing patients can lead to additional workload for healthcare professionals. We must ensure they receive support and that the additional workload from EHDS is not excessive.

### Health data sharing for secondary use

The EHDS must take into account potential issues around interoperability, as this can significantly hinder health data sharing.



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- Codes can be different in different countries making cross-border exchange difficult and a common data model would be helpful. In addition, if different techniques to strip the data are applied without a common format this can become complicated.

The responsibilities of data holders must be clearly defined and take into account the challenges that small organisations, non-profit organisations, researchers and medical societies may face.

- Medical Societies will be both users and contributors to EHDS in their activities e.g., in representing healthcare professionals, contributing to health research and clinical trials and through their efforts to establish and maintain registries.
- There should be some sort of support, capacity building and resources for small organisations, non-profit organisations, researchers and medical societies, to help them comply with the provisions of the EHDS.

We welcome the broad list of allowed purposes for the secondary use of health data as mentioned in article 34 of the proposal.

- We believe that a broad list of purposes is essential to advance European health research, provided that the necessary safeguards are in place.

We should work towards a new generation of ethics committees which have the capacity to manage the specifics of ethical use of health data for research.

- The current Regulation states that a user may need ethical approval if that is required in their member state, and this could add to the complexity.
- We are also concerned that current ethics committees and data protection authorities are not fully prepared to fulfil their role in the regulation in assessing requests for access to pseudoanonymised data. A new era of data ethics may be needed to take ethical principles of medical research and apply it to the specificities of use of data for health research.
- The EHDS should clarify what is in the remit of ethics committees when such assessment (for secondary use of data) is performed, what is expected from the researcher, especially since research on data originating from different EU Member States and is still subject to national laws, putting the researcher in difficulty to be aware and to comply with such laws.

Clarifications are necessary on the making available of clinical trial data

- To avoid fragmentation, confusion and lack of clarity on how this Regulation applies to clinical trial data, the EC should ensure there are clear timescales given for when access to clinical trial data should be granted to national health data agencies. This should take into account the needed data maturity aspects and avoid opportunistic use of the data before their publication by the research team having generated those data. Of course, such publication should happen within a reasonable time frame.

### **Regulatory clarity**

The new regulation must provide the necessary regulatory clarity and harmonisation around health data sharing, without adding additional complexity to a situation where already many legislations overlap, and national or local interpretations differ.



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- The current EU landscape is complex, and the EHDS will interplay with regulations like the General Data Protection Regulation (GDPR)<sup>1</sup>, the Medical Devices Regulation (MDR), In Vitro Diagnostics Regulation (IVDR), Regulation on Artificial Intelligence, Clinical Trials Regulation, Data Governance Act, Data Act and others. Appropriate guidance is needed to navigate the overlap and the legislative system must not become unnecessarily complex.
- At the same time, we have experienced that the GDPR is interpreted differently across member states and sometimes even at local level, forming an additional barrier to conducting collaborative health research. We must ensure that EHDS does not add to the complexity in health research but is implemented and interpreted in a harmonised way.
- EU wide implementation guidance and/ or Codes of Conduct for compliance with the relevant pieces of EU legislation such as GDPR would be extremely welcome to overcome the current fragmentation.

### Stakeholder involvement

The EHDS envisions significant change from the current status quo. The vision can only be built with the stakeholders that will provide and access the data, and we must ensure appropriate and structural stakeholder involvement from the early stages of the development to the implementation and operation. This will be essential in terms of ensuring the scientific return on investment and embedding the societal gains, which ultimately must be around better health, and better patient care.

- We know that all aims of the EHDS are achieved better through collaboration. No single player can deliver these aims in isolation.
- Stakeholder engagement needs to be better defined and there needs to be a strong mechanism for ensuring involvement of stakeholders and experts to provide scientific advice.
- Patients, healthcare professionals, organisations managing registries, and industry need to be better involved and have clearer roles in order to enhance trust in the system, specifically in the European Board.
- EHDS should be designed to be maximally useful for clinicians and patients, by gathering their feedback and updating as needed.

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<sup>1</sup> on 11/02/2021, the Commission published a study on the “Assessment of the EU Member States’ rules on health data in the light of GDPR” [6]. The study finds that while the GDPR lays down horizontal directly applicable rules in all Member States, there remains variation in the range of national-level legislation linked to its implementation in the area of health. This study reveals a fragmented approach in the way that health data processing for health and research is conducted in the Member States. This can negatively impact cross-border cooperation for care provision, healthcare system administration, public health or research. The conclusion of the study was that *“whatever next steps are chosen by EU policy makers, it is clear that co-operation between Member States is crucial. Such co-operation should also fully take into account the interests of the key stakeholders, in particular patients, healthcare professionals, healthcare providers, researchers, industry and also health and data protection authorities.*



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- There should be a scientific return of investments to participating actors that put time or expertise into contributing to EHDS.

We must invest to ensure that patients, healthcare professionals and researchers have the right skillset to participate in EHDS.

- There is a clear need for policies and programmes to improve digital literacy of patients, healthcare professionals and researchers so they can effectively contribute to and use the EHDS. Capacity building should not begin and end with government agencies, but must permeate all levels of health systems.
- Particular attention must be given to ensure certain groups and subgroups are not excluded from digital advancement.

Overall, there is also a need for transparency in the development, implementation and management of EHDS.



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### Annex: Examples of health data sharing

Examples of health data sharing provided by BioMed Alliance members highlighting how the aspects presented in the response relate to their concrete experience with health data sharing.

Representative of Organisation	Sentence/part of the statement that example relates to	Description of the example or case study
ERN eUROGEN	<p>Differing interpretation GDPR</p> <p>Stakeholder involvement</p> <p>Regulatory complexity</p>	<p>There are 5 ERN registries, 19 under development including the ERN eUROGEN one which went live this year. We have encountered large differences across the Member States and many different local rules and procedures, which are blocking or delaying the implementation of the ERN registries. GDPR barriers are more numerous than ethical and legal issues. Clinical teams need more support from their healthcare providers to deal with local issues on GDPR and to input data into the ERN registries. This should be coordinated at management level and ideally automated via IT departments as some healthcare providers can be members of all 24 ERNs.</p> <p>It is planned that the 24 ERN registries will be the pilot for the EHDS. Patients are involved in the ERN registry governance structures, working along the clinicians, including the data access committees. It is very important they are involved in any European level governance structures for the EHDS as their contribution to how their data is used is vital.</p> <p>Translation of EHDS guidance and regulatory information will be needed.</p>
EULAR	<p>Differing interpretation GDPR</p>	<p>In a non-pharmacological cluster trial, with ethics approval at the coordinating centre, each participating centre's ethics committee mandated to add a different sentence on data protection.</p>
EULAR	<p>Need for regulatory clarity and harmonisation around health data sharing</p>	<p>In a multinational registry of allergic diseases, each country, region, centre, had to review exactly the same information and the data protection requirements would vary across centres. Some centres were not able to participate due to the interpretation of the committee.</p>
EULAR	<p>Medical Societies acting as users and contributors to EHDS</p>	<p>In a multinational volunteer (unpaid) registry, some centres alluded to European legislation to solicit contracts with the European medical society. This multinational registry is extremely difficult to launch with each centre requesting different paperwork.</p>



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EAU	Secondary Use of Data	<p>We coordinate two IMI funded projects on use of Big Data. One is <a href="#">PIONEER</a> on use of big data to assist in answering the unanswered questions on prostate cancer. These research needs have been defined by clinicians and patients. Then, there is <a href="#">OPTIMA</a> which is using Big Data to develop data driven AI tools to support clinical decision making in prostate, lung and breast cancers.</p>
EORTC	Secondary Use of Data	<p><a href="#">EMA- Secondary-use-of-health-data Discussion-Paper Stakeholders-consultation.pdf (eortc.org)</a></p> <p>Since its implementation, GDPR did not lead to the failure of any of EORTC trials, studies or research projects. However, in two occasions we lost US based academic partners afraid of GDPR related risks, in one occasion a clinical trials was rejected for unjustified GDPR related reasons (where an EC was clearly acting beyond its remits) and, in general, the lack of harmonisation and/or clarity around questions we raise in this document costed EORTC numerous hours of work. Namely to its Privacy Office, Regulatory Affairs and Contract Departments. The time and efforts spent on the updates of documents, including hundreds and more contracts applicable to ongoing research (work still in progress) is in our view of a little added value as compared to yet to be proved gain of protection to data subjects. Therefore, we call all EU relevant bodies (EMA, EU Commission, EDPB, DPAs) to urgently clarify, harmonise and provide viable solutions to avoid seriously harming health research and innovation in Europe.</p> <p>For instance: the term 'genetic data'. GDPR has one definition. EU Member States (MSs) sometimes have different definitions and impose different conditions, in relation to their own definition. One example is that consent as legal basis is imposed without leaving any choice to the data controller (France, Germany, Italy). In other countries, conditions may include stricter access conditions which shall rely on biometric identification means (Italy).</p> <p>Other example: Who decides on the legal basis? In our understanding of the law, when an entity is the Sponsor of research (or legal responsible) it also becomes the data controller of the processing of personal data in scope of the research (or at least one of data controllers</p>



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		<p>whether joint or independent). Under the GDPR, the obligation to set up the legal ground for processing personal data resides with the data controller. Nevertheless, this is one aspect which we have faced during initial submissions to regulatory bodies, as of May 2018: ethics committees (ECs) that impose the legal basis (frequently consent in their template patient information sheet) for processing personal data in scope of research and in particular requested collection of consent of the patient in case of secondary use. Sometimes the opinion of ECs is even in contradiction with the recommendations of EDPB and/or national experts in the field (including DPAs). In EORTC opinion, it is not up to the ECs to decide on a specific legal basis.</p>
EHA	Health data sharing for secondary use / Interoperability	<p><a href="#">HARMONY</a> is a multidisciplinary public-private partnership that aims at collecting and harmonizing health records on the diagnosis, treatment, and outcomes of patients with blood cancer.</p> <p>To ensure that the descriptive, comparative, and predictive information generated by the analyses performed on the data platform is reliable, the input information is checked precisely, to ensure it is standardized, anonymized, complete, and correct.</p> <p>HARMONY has developed data security and data processing standards consistent with EU and national regulations on data exchange, privacy, and ethical rules. This novel approach has become a blueprint for similar projects. The HARMONY Anonymization Concept was designed to comply with GDPR without impacting the clinical value of the relevant data.</p> <p>Another essential step is to convert all the data to the <a href="#">OMOP</a> common data model. This determines the usability and value of the output data. It does not affect the meaning or the clinical value of the data, but it does allow information that was initially incomparable and not interoperable to be processed in a standardized way.</p>
EHA	<p>Secondary use of data</p> <p>responsibilities of data holders &amp; challenges that small organisations, non-profit</p>	<p><a href="#">RADeep</a>, the Rare Anaemia Disorders European Epidemiological Platform, is an initiative conceived in the core of ERN-EuroBloodNet as an umbrella for both new and already existing European patients' registries in rare anaemia disorders (RAD).</p> <p>RADeep is built in line with <a href="#">ENROL</a>, the ERN-EuroBloodNet central platform for European patients' registries on rare haematological diseases, and the EU-</p>



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	<p>organisations, researchers and medical societies face</p> <p>Collaboration</p>	<p>RD-Platform recommendations for patients' registries on rare disorders. RADeep contributes to ENROL sharing pseudonymised data of patients affected by a rare anaemia disorder throughout Europe.</p> <p>RADeep will allow mapping at the European level not only the methods for diagnosis and the main clinical features and treatments of patients affected by a rare anaemia disorder, but also demography and survival rate, in order to facilitate the access to specialized and adequate healthcare and engage research and development of new treatments, thus increasing the knowledge and promoting best practices across EU.</p> <p>Accordingly, a legal frame for RADeep secure sharing and re-use of data on patients affected by RAD enabling both entering certified medical data from available sources and re-use of data with third parties, namely other ERNs, research community and industry has been established from the outset.</p>
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