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Biomedical Alliance in Europe

Suggested amendments to the Proposal for a European Health Data Space

Prepared by medical and research societies part of the Biomedical Alliance in Europe

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Introduction

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 and research societies, welcomes the intention to reduce barriers to data sharing and to ensure that patients, healthcare professionals and researchers have better access to data.

After extensive discussions with researchers, healthcare professionals and policy experts in our Health Data Taskforce, we would like to suggest several amendments that we believe will improve the implementation of EHDS and make sure it can have a concrete positive impact on the healthcare and research sectors and ultimately on the life of patients.

Our views on the EHDS proposal

We believe that the following aspects should be considered[1] 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:

- We must ensure synergies between EHDS for primary and secondary health data sharing.
- 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.
- The EHDS must take into account potential issues around interoperability, as this can significantly hinder health data sharing.
- 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.
- We welcome the broad list of allowed purposes for the secondary use of health data as mentioned in article 34 of the proposal, as it is necessary to reduce barriers to health data sharing in research to lead to better outcomes for patients.
- 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 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.
- 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 must invest to ensure that patients, healthcare professionals and researchers have the right skillset to participate in EHDS.
- Overall, there is also a need for transparency in the development, implementation and management of EHDS.

[1] Read more here

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Suggested Amendments

Original text	Proposed amendment	Justification
Recital 61 (61) Cooperation and work is ongoing between different professional organisations, the Commission and other institutions to set up minimum data fields and other characteristics of different datasets (registries for instance). This work is more advanced in areas such as cancer, rare diseases, and statistics and shall be taken into account when defining new standards. However, many datasets are not harmonised, raising comparability issues and making cross-border research difficult. Therefore, more detailed rules should be set out in implementing acts to ensure a harmonised provision, coding and registration of electronic health data.	**Recital 61 (also proposed by ESC)** 61) Cooperation and work is ongoing between different professional organisations, the Commission and other institutions to set up minimum data fields and other characteristics of different datasets (registries for instance). This work is more advanced in areas such as cancer, rare diseases, and statistics and shall be taken into account when defining new standards. However, many datasets are not harmonised, raising comparability issues and making cross-border research difficult. Therefore, more detailed rules should be set out in implementing acts to ensure a harmonised provision, coding and registration of electronic health data. **Existing health data infrastructures and registries put in place by institutions and stakeholders can contribute to defining and implementing data standards, to ensuring interoperability and must be leveraged to allow continuity and build on existing expertise.**	**Justification** The EU institutions shall cooperate with medical societies, to leverage existing successful initiatives and related expertise, which can highly contribute to cross-border interoperability. In addition, the implementation of this type of compulsory structured data in the EHR infrastructure through the EHDS might improve cost-effectiveness in medical documentation. EHDS must leverage the significant work in terms of standardisation and harmonisation already achieved by medical registries
Recital 69 (69) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the	**Recital 69 (also proposed by ESC)** (69) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European	**Justification** Stakeholders, and in particular healthcare professionals, need to be consulted in the drafting process of implementing acts, as their expertise can highly contribute to interoperability and to the harmonised implementation of the Regulation. Medical societies can play a key role also due to

European Parliament and of the Council.	Parliament and of the Council. **In accordance with the Inter-Institutional Agreement of 13 April 2016 on Better Law-Making, the Commission will make use of expert groups, consult targeted stakeholders and carry out public consultation to gather broader expertise in the early preparation of draft implementing acts. In particular, healthcare professionals and patients' representatives shall be consulted.**	their direct experience with cross-border health data registries and to their coordination role for healthcare professionals across Europe. For instance, healthcare professionals shall be consulted in the definition of data registration requirements, due to the direct impact on their daily clinical activities, and they can crucially contribute to the identification of technical specifications for the electronic health record exchange format and of the minimum specifications for cross-border datasets.
Article 2 – paragraph 2 y (y) 'data holder' means any natural or legal person, which is an entity or a body in the health or care sector, or performing research in relation to these sectors, as well as Union institutions, bodies, offices and agencies who has the right or obligation, in accordance with this Regulation, applicable Union law or national legislation implementing Union law, or in the case of non-personal data, through control of the technical design of a product and related services, the ability to make available, including to register, provide, restrict access or exchange certain data;	**Article 2 – paragraph 2 y**	**Justification** We believe this definition may lead to confusion and misinterpretation and should be streamlined.
Article 45 – paragraph 4 b (b) information on the assessment of ethical aspects of the processing**, where applicable and in line with national law.**	**Article 45 – paragraph 4 b** (b) information on the assessment of ethical aspects of the processing, where applicable.~~ and in line with national law~~.	**Justification** The power of the EHDS is in providing a more aligned approach to data-reuse for research, policy making and regulatory purposes. In order to leave space for the possibility of future aligned approach to ethical approval processes during implementation of the EHDS, including

		harmonisation of approach and data permits, and European research (cross border) the removal of the mention of national law allows for future harmonised standards.
Article 54 – Paragraph 2 2. A data permit issued by one concerned health data access body may benefit from mutual recognition by the other concerned health data access bodies.	**Article 54 – Paragraph 2** A data permit issued by one concerned health data access body may benefit from mutual recognition by the other concerned health data access bodies. **Similarly, an ethics committee approval from one member state may benefit from mutual recognition by the concerned health data access bodies.**	**Justification** The mutual recognition mechanisms for cross border data permits must be strengthened, balancing the efforts when protecting data of a certain level of anonymization [2],[3]. One area which will facilitate this is a mutual recognition of ethical approvals.
Article 59 The Commission shall support sharing of best practices and expertise, aimed to build the capacity of Member States to strengthen digital health systems for primary and secondary use of electronic health data. To support capacity building, the Commission shall draw up benchmarking guidelines for the primary and secondary use of electronic health data.	**Article 59** The Commission shall support sharing of best practices and expertise, aimed to build the capacity of Member States to strengthen digital health systems for primary and secondary use of electronic health data. **With reference to Art 33.1 (i), appropriate capacity-building measures should be planned and resources allocated to support non-profit organizations, researchers and medical societies in complying with their duties as data holders for their registries.** To support capacity building, the Commission shall draw up benchmarking guidelines for the primary and secondary use of electronic health data.	**Justification** Healthcare professionals, researchers and patients are key groups that will contribute to and benefit from the EHDS through registries (often cross border) that have been developed on a number of issues, technologies and conditions. They need the necessary resources, skills and information to effectively contribute and therefore support for training should be foreseen in the regulation.

[2] Pseudonymization vs anonymization: differences under the GDPR - Statice

[3] France: CNIL issues statement on anonymisation of personal data | DataGuidance

Article 64 – Paragraph 1	**Article 64 – Paragraph 1 (also proposed by E.C.O.)** 1. A European Health Data Space Board (EHDS Board) is hereby established to facilitate cooperation and the exchange of information among Member States. The EHDS Board shall be composed of the high-level representatives of digital health authorities and health data access bodies of all the Member States, **as well as not less than one representative from a European level patient organisation, and not less than one representative of a European level healthcare professional organisation.**	**Justification** Patients and healthcare professionals are critical end users of the European Health Data Space. Ensuring their active participation in the governance of the European Health Data is critical to ensuring trust, improving implementation and achieving a continuously improving European Health Data Space.
Article 64 – Paragraph 4 4. Stakeholders and relevant third parties, including patients' representatives, shall be invited to attend meetings of the EHDS Board and to participate in its work, depending on the topics discussed and their degree of sensitivity.	**Article 64 – Paragraph 4** 4. Stakeholders and relevant third parties, including **healthcare professionals, researchers and** patients' representatives, shall be invited to attend meetings of the EHDS Board and to participate in its work **on a structural basis**, depending on the topics discussed and their degree of sensitivity.	**Justification** Stakeholder involvement in the EHDS Board should happen on a more structural basis, as healthcare professionals, researchers and patients are the core users and contributors to EHDS. They can therefore provide essential information related to the coordination, implementation and operation of EHDS.
Article 65 – Paragraph 2 b xiii (new) (xii) technical specifications or existing standards regarding the requirements set out in Chapter IV; (xiii) incentives policy for promoting data quality and interoperability improvement;	**Article 65 – Paragraph 2 b xiii (new)** (xii) technical specifications or existing standards regarding the requirements set out in Chapter IV; **(xiii) specifications on ethical principles for data reuse for ethical committees to assist mutual recognition.**	**Justification** The World Medical Association's Declaration of Helsinki, and the Declaration of Taipei serve as the basis for ethical principles in clinical research involving humans, biobanks and health databases. However, there is a gap of specific international ethical guidance for ethical re-use of health data

	(xiv) incentives policy for promoting data quality and interoperability improvement;	for research. The ethical principles of justice, beneficence and respect to humans and human autonomy require specific and targeted ethical consideration. The EHDS implementation will require a specific and clear ethical framework for data re-use.
Article 65 – Paragraph 2 b xiii (new) (xii) technical specifications or existing standards regarding the requirements set out in Chapter IV; (xiii) incentives policy for promoting data quality and interoperability improvement;	**Article 65 – Paragraph 2 b xiii (new)** (xii) technical specifications or existing standards regarding the requirements set out in Chapter IV; (xiii) incentives policy for promoting data quality and interoperability improvement; **(xiv) guidance on risk based de-identification processes for the European Health Data Space, building on what has already been learned from previous and current EU research infrastructures and funded projects.**	**Justification** Depending on the degree of de-identification, the terms pseudonymization or anonymization are often used. Different methods used to achieve appropriate de-identification have distinct advantages and disadvantages and the appropriate choice depends on many factors (e.g., the degree of risk, the way the data is processed, etc). The EHDS foresees a process to minimize risk (for example through the use of health data authorities, data permits and secure processing environments). This Regulation will benefit from an aligned interpretation of de-identifcation for the purposes of the EHDS, which is compatible with horizontal EU legislation. Much has already been accomplished in this regard by former and current European research infrastructures and programmes (such as the IMI Big Data for Better Outcomes projects and the EMA DARWIN initiative) which should be transformed into a living guideline for de-identification for the purposes of EHDS.

Article 65 – Paragraph 2 f (f) to facilitate the **exchange of views on the secondary use of electronic health data with the relevant stakeholders, including representatives of patients, health professionals, researchers, regulators and policy makers in the health sector.**	**Article 65 – Paragraph 2 f** (f) to facilitate the **creation of a stakeholder forum which meets no less than twice a year, including representatives of patients, health professionals, researchers, regulators, industry representatives and policy makers in the health sector to support the co-design of aligned implementation strategies, guidance and standards and to provide a forum to assess the needs of the broader ecosystem.**	**Justification** The EHDS will require broad stakeholder support and acceptance to be effectively implemented in a broad ecosystem. The creation of a stakeholder forum clearly delineates a structure for engagement with the broad community of stakeholders.
Article 65 – Paragraph 2 g (new)	**Article 65 – Paragraph 2 g (new)** **(g) To support and coordinate the action of all relevant national and European competent authorities, ethics committees and external stakeholders to develop an authoritative and harmonised European code of conduct on the reuse of health data for research. This code should include harmonized, efficient & consistent tools for implementing and monitoring the compliance for all stakeholders.**	The EHDS should support the development of an authoritative European Code of Conduct on the re-use of health data for research purposes. This could be in line with the provisions of Article 40 GDPR codes of conduct.
Article 67 – Paragraph 4 4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Inter-institutional Agreement of 13 April 2016 on Better Law-Making.	**Article 67 – Paragraph 4 (also proposed by ESC)** 4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State **and targeted stakeholders, including health professionals and patients' organisations,** in accordance with the principles laid down in the Inter-institutional Agreement of 13 April 2016 on Better Law-Making.	Stakeholders, and in particular healthcare professionals, need to be consulted in the drafting process of delegated acts, as these will add or amend aspects of the Regulation with a crucial impact on their clinical and research activities. Healthcare professionals can share useful views, expertise and evidence for the definition of such elements, including additional priority categories of data to be included in the EHDS and their

		characteristics, the duties of the data holders, the principles and requirements for data quality and utility label. We feel it is important to include this specification in addition to the existing reference (only) to experts at national level.
Article 68 – Paragraph 3 (new) 1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011. 2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.	**Article 68 – Paragraph 3 (new, also proposed by ESC)** 1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011. 2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply. **3. In accordance with the Inter-Institutional Agreement of 13 April 2016 on Better Law-Making, the Commission will make use of expert groups, consult targeted stakeholders and carry out public consultations to gather broader expertise in the early preparation of draft implementing acts.**	Stakeholders, and in particular healthcare professionals, need to be consulted in the drafting process of delegated acts, as these will add or amend aspects of the Regulation with a crucial impact on their clinical and research activities. Healthcare professionals can share useful views, expertise and evidence for the definition of such elements, including additional priority categories of data to be included in the EHDS and their characteristics, the duties of the data holders, the principles and requirements for data quality and utility label. We feel it is important to include this specification in addition to the existing reference (only) to experts at national level.

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	Differing interpretation GDPR Stakeholder involvement Regulatory complexity	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. 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. Translation of EHDS guidance and regulatory information will be needed.
EULAR	Differing interpretation GDPR	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.
EULAR	Need for regulatory clarity and harmonisation around health data sharing	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.

EULAR	Medical Societies acting as users and contributors to EHDS	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.
EAU	Secondary Use of Data	We coordinate two IMI funded projects on use of Big Data. One is **PIONEER** 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 **OPTIMA** which is using Big Data to develop data driven AI tools to support clinical decision making in prostate, lung and breast cancers.
EORTC	Secondary Use of Data	**EMA-_Secondary-use-of-health-data_Discussion-Paper_Stakeholders-consultation.pdf (eortc.org)** 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. 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). 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 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.
EHA	Health data sharing for secondary use / Interoperability	**HARMONY** 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. 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. 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. Another essential step is to convert all the data to the **OMOP** 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.
EHA	Secondary use of data responsibilities of data holders & challenges that small organisations, non-profit organisations, researchers and medical societies face Collaboration	**RADeep**, 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). RADeep is built in line with **ENROL**, the ERN-EuroBloodNet central platform for European patients' registries on rare haematological diseases, and the EU-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. 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. 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.