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Biomedical Alliance in Europe

Reaction to draft ENVI-LIBE Report on EHDS from 10.02.2023

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 share our views on the Draft Report of the ENVI-LIBE Committees on the proposal for a regulation on the European Health Data Space from 10 February 2023. We will also suggest several additional 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 general 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 EHDS, 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

Biomedical Alliance in Europe

Reaction to amendments proposed in draft ENVI/LIBE report

Amendment as stated in ENVI/LIBE draft report	Our comments
Amendment 2, Recital 5 a (new) ***(5a) Although Regulation 2016/679 does not apply to the personal data of deceased persons, such data, in particular health data, may constitute personal data of the relatives of deceased persons and create certain risks. Member States are encouraged to allow either a person appointed by the data subject during their life or a close relative, if a close relative has a legitimate interest in such protection or for family reasons worthy of protection, to exercise the data subject's rights of deceased person arising from this Regulation after their death, in particular to fully or partially opt-out of having some or all of their personal electronic health data processed for secondary use. Data holders should ensure that data of deceased individuals is kept in a way that ensures its confidentiality, in particular by applying relevant technical and organisational measures, and is respectful to the deceased individuals and their relatives. Member States are encouraged to allow data subjects to establish instructions for the management of their personal data after death. In case where a data subject has expressly forbidden it with a written declaration, exercise of data subject rights by an appointed person or a close relative should not be permitted.***	We are of the opinion that this addition may be problematic as it is adding additional requirements to that of GDPR, particularly for a system where we have a data minimisation requirement – and where most data will be anonymised or pseudonymised data sets. The concepts of rights of deceased people goes further than existing human rights instruments. We also believe a retroactive opt-out after a person's death may affect ongoing health research activities.
Amendment 7, Recital 18a (new) ***(18 a) In order to support the successful implementation of the EHDS and the execution of an effective landscape of European health data cooperation, the Commission should agree with Member States a range of time-based targets for implementation of health data interoperability milestones, including in respect to cancer registry interoperability.***	We would suggest to change the last sentence to: '***including in respect to cancer and other disease registries' interoperability***' to include the wide variety of disease registries in the health field.
Amendment 10, Recital 36 a (new) ***(36a) Facilitating the use of real-world data offers benefits for policy and***	We fully support this amendment.

regulatory decision-making, research, clinical, and health technology assessment purposes. Real-world evidence complements randomized clinical trial data and enables a holistic understanding of medicines' effectiveness, impact and safety in large and heterogeneous populations. It is particularly crucial for policy and regulatory decision-making in certain disease areas, including respiratory or rare diseases. On top of enabling better health outcomes for patients, the more intensive use of realworld evidence also offers economic benefits and can contribute to the greater sustainability of health systems.	
Amendment 11, Recital 37 (37) For the secondary use of ***electronic health*** data for research, innovation, policy making, regulatory purposes, patient safety or the treatment of other natural persons, the possibilities offered by Regulation (EU) 2016/679 for a Union law should be used as a basis for rules and mechanisms and providing suitable and specific measures to safeguard the rights and freedoms of the natural persons. ***For processing of electronic health data for secondary use, a legal basis set out in Article 6(1)(c), (e) or (f) combined with a legal basis set out in Article 9(2) of Regulation (EU) 2016/679 is required. The most relevant processing grounds listed in Article 9(2) of Regulation (EU) 2016/679 in this context concern the provision of health or social care (point (h)), substantial public interest (point (g)), public interest in the area of public health (point (i)) and research (point (j)). Hence,*** this Regulation provides the legal basis in accordance with Articles 9(2) (g), (h), (i) and (j) of Regulation (EU) 2016/679 for the secondary use of health data, establishing the safeguards for processing, in terms of lawful purposes, trusted governance for providing access to health data (through health data access bodies) and processing in a secure environment, as well as modalities for data processing, set	We believe this amendment may lead to unnecessary legal complexity.

out in the data permit. More specifically, for processing of electronic health data held by the data holder pursuant to this Regulation, this Regulation creates the legal obligation in the sense of Article 6(1) point (c) of Regulation (EU) 2016/679 for disclosing the data by the data holder to health data access bodies, while the legal basis for the purpose of the initial processing (e.g. delivery of care) is unaffected. This Regulation assigns tasks in the public interest to the health data access bodies (running the secure processing environment, processing data before they are used, etc.) in the sense of Article 6(1)(e) of Regulation (EU) 2016/679, and meets the requirements of Article 9(2)(h),(i),(j) of the Regulation (EU) 2016/679. ***At the same time, the data applicant should demonstrate a legal basis pursuant to Article 6 of Regulation (EU) 2016/679, combined with Article 9(2) thereof, based on which they could request access to data pursuant to this Regulation and should fulfil the conditions set out in Chapter IV of this Regulation.*** In the case where the user has access to electronic health data (for secondary use of data for one of the purposes defined in this Regulation), the data user should demonstrate the specific legal basis on which it relies as part of the application for access to electronic health data pursuant to this Regulation: on the basis of the applicable legislation, where the legal basis under Regulation (EU) 2016/679 is Article 6(1), point (e), or on Article 6(1), point (f), of Regulation (EU) 2016/679. If the user relies upon a legal basis offered by Article 6(1), point (e), it should make reference to another EU or national law, different from this Regulation, mandating the user to process personal health data for the compliance of its tasks. If the lawful ground for processing by the user is Article 6(1), point (f), of Regulation (EU) 2016/679, in this case it is this Regulation that provides the ***appropriate and necessary*** safeguards. In this context, the	

data permits issued by the health data access bodies are an administrative decision defining the conditions for the access to the data.	
Amendment 13, Recital 39 a (new) ***(39a) A relationship of trust between patients and health or care providers is a crucial element of the provision of health or social care or treatment. It is within that delicate context that patients should have a say in the processing of their health data for secondary use. It is appropriate to empower patients- data subjects- by giving them the possibility to restrict access to all or parts of their personal data for all or parts of secondary use and to provide for obligations to clearly inform data subjects of this possibility. Therefore, an opt-out for data subjects for secondary use of their electronic health data should be envisaged, as the purpose of the secondary processing causes the patient's individual interests to prevail over the general interest of society.***	BioMed Alliance and the medical societies that it represents believe that we should do everything possible to facilitate health data sharing for research, while sufficiently protecting patient privacy and patient safety. We believe that sharing health data for research is in the interest of the patient. We also believe that a model based on informed consent or on opt-in would put additional pressure on healthcare professionals and would hinder health research. Therefore, we support an opt-out model could be an appropriate compromise, where practicable.
Amendment 16, recital 49 (49) Given the sensitivity of electronic health data, it is necessary to reduce risks on the privacy of natural persons by applying the data minimisation principle as set out in Article 5 (1), point (c) of Regulation (EU) 2016/679. Therefore, the use of anonymised electronic health data***,*** which ***ensures, to the maximum extent possible, by making use of state-of-the art technologies, that a person cannot be reidentified,*** should be made available when possible and if the data user asks it. If the data user needs to use identifiable personal electronic health data, it should clearly indicate in its request the justification for the use of this type of data for the planned data processing activity. The personal electronic health data should only be made available in pseudonymised format and the encryption key can only be held by the health data access body. Data users should not attempt to re-identify natural persons from the dataset provided under this	BioMed Alliance believes that adding these sentences here is not necessary and adds to unnecessary complexity, the first sentence already indicates that risks should be reduced. We believe that the regulation already favours using anonymised data over pseudonymised and that risks are sufficiently addressed.

Regulation, subject to administrative or possible criminal penalties, where the national laws foresee this. ***It should be underlined that the application of pseudonymisation to personal data can only reduce the risks to the data subjects concerned but cannot exclude them.*** However, this should not prevent, in cases where the results of a project carried out based on a data permit has a health benefit or impact to a concerned natural person (for instance, discovering treatments or risk factors to develop a certain disease), the data users would inform the health data access body, which in turn would inform the concerned natural person(s). Moreover, the applicant can request the health data access bodies to provide the answer to a data request, including in statistical form. In this case, the data users would not process health data and the health data access body would remain sole controller for the data necessary to provide the answer to the data request.	
Amendment 18, Recital 54 (54) Given the sensitivity of electronic health data, data users should ***only have restricted*** access to such data***, in accordance with the data minimisation principle***. All secondary use access to the requested electronic health data should be done through a secure processing environment. In order to ensure strong technical and security safeguards for the electronic health data, the health data access body should provide access to such data in a secure processing environment, complying with the high technical and security standards set out pursuant to this Regulation. Some Member States took measures to locate such secure environments in Europe. The processing of personal data in such a secure environment should comply with Regulation (EU) 2016/679, including, where the secure environment is managed by a third party, the requirements of Article 28 and, where applicable, Chapter V. Such secure processing environment should reduce the privacy risks related to such processing	We believe it is not necessary to mention that 'users should only have restricted access to data' and that data sharing should be 'in accordance with the data minimisation principle'. The text of the recital already refers to the need to comply with high security standards set out pursuant to the regulation, and that processing of personal data in a secure environment should comply with GDPR which already mentions the need for data minimisation in article 5(1)(c).

activities and prevent the electronic health data from being transmitted directly to the data users. The health data access body or the data holder providing this service should remain at all time in control of the access to the electronic health data with access granted to the data users determined by the conditions of the issued data permit. Only non-personal electronic health data which do not contain any electronic health data should be extracted by the data users from such secure processing environment. Thus, it is an essential safeguard to preserve the rights and freedoms of natural persons in relation to the processing of their electronic health data for secondary use. The Commission should assist the Member State in developing common security standards in order to promote the security and interoperability of the various secure environments.	
Amendment 22, Recital 63(a) new ***(63a) The initial Union funding to achieve a timely application of the EHDS is limited to what can be mobilised under the 2021-2027 Multiannual Financial Framework (MFF) where 220 million euro can be made available under the EU4Health and Digital Europe programmes. The successful and coherent application of the EHDS across all Member States will however require a higher funding. The Commission should therefore analyse the need for mobilising further resources for the EHDS as part of the review of the 2021-2027 MFF and for the forthcoming MFF under the principle that new initiatives should be matched with new funding.***	We support the call for strong funding for EHDS under the current and future MFF.
Amendment 27, Recital 65 (65) In order to promote the consistent application of this Regulation, a European Health Data Space Board (EHDS Board) should be set up***. The Board should consists of representatives from digital health authorities, European Data Protection Board, European Data Protection Supervisor, European Medicines Agency, European Centre for***	We very much welcome the inclusion of healthcare professionals and patients as they will be the future users, contributors and those who benefit from the EHDS. They should be closely involved in the preparation, implementation and operation.

Disease Prevention and Control, healthcare professionals, patient organizations, and health industry. All Board members have the same rights and responsibilities. Furthermore, experts of the European Parliament should be invited to attend the meetings of the EHDS Board. The EHDS Board may also invite experts and observers to attend its meetings, and may cooperate with other external experts as appropriate. The EHDS Board should operate transparently with open publication of meeting dates and minutes of the discussion as well as an annual report. *The Commission should participate in its activities and chair it. It should contribute to the consistent application of this Regulation throughout the Union, including by helping Member State to coordinate the use of electronic health data for healthcare, certification, but also concerning the secondary use of electronic health data. Given that, at national level, digital health authorities dealing with the primary use of electronic health data may be different to the health data access bodies dealing with the secondary use of electronic health data, the functions are different and there is a need for distinct cooperation in each of these areas, the EHDS Board should be able to set up subgroups dealing with these two functions, as well as other subgroups, as needed. For an efficient working method, the digital health authorities and health data access bodies should create networks and links at national level with different other bodies and authorities, but also at Union level. Such bodies could comprise data protection authorities, cybersecurity, eID and standardisation bodies, as well as bodies and expert groups under Regulations […], […], […] and […] [Data Governance Act, Data Act, AI Act and Cybersecurity Act].* ***However, data protection issues, including the interpretation or the application of data protection rights and the identification or***	

the handling of data breaches related to primary and secondary use of electronic health data, should remain the exclusive competence of the data protection authorities.	
Amendment 37, Article 2(2)(m) (m) 'EHR' (electronic health record) means a collection of electronic health data related to a natural person and collected in the health system, processed for ***the purpose of the provision of*** healthcare ***services***;	We wonder what the reasoning behind this amendment is, we believe EHRs can also play a role in patient care in the context of health research and clinical trials.
Amendment 45, Article 3, (5) (1) (b) ***(b a) allow electronic health data access services to interface with electronic health records, products and applications under strict security, confidentiality and consent conditions.***	We believe the part relating to consent should be removed to avoid uncertainty, making the new text: ***(b a) allow electronic health data access services to interface with electronic health records, products and applications under strict security and confidentiality conditions.***
Amendment 58 Article 10(2)(m) (m) cooperate with other relevant entities and bodies at national or Union level, to ensure interoperability, data portability and security of electronic health data, as well as with stakeholders representatives, including patients' representatives, healthcare providers, health professionals, ***including professional associations representing them,*** industry associations;	We fully support this amendment.
Amendment 60 Article 10(5) **5. *Essential health stakeholders representatives on national level, including patient organisations, and healthcare professionals, shall be present in the governance and decision-making structures of the digital health authority.*** In the performance of its tasks, the digital health authority shall actively cooperate with stakeholders' representatives, including patients' representatives. Members of the digital health authority shall avoid any conflicts of interest. ***The Commission may adopt guidance on what is likely to constitute a conflict of interests together with the procedure to be followed in such cases.***	We support the inclusion of health stakeholders. We would also like to note that appropriate conflict of interest policies are welcome and necessary, but they should take into account the different hats that clinicians and researchers wear and find an appropriate balance taking into account the realities in the health system.

Amendment 80, Article 33(1)(j) (j) electronic health data from ***fully completed*** clinical trials *and* ***in accordance with Regulation (EU) No 536/2014*****;**	We believe it is beneficial to align with the clinical trials Regulation, but the wording 'fully completed' should be amended to 'fully completed or terminated' or removed. From an academic health research perspective, data from e.g. discontinued trials due to safety or effectiveness signals would still be useful to be included.
Amendment 84, Article 33(5) Natural ***persons that are subjects to secondary use of health data shall have the right to decline the processing of their health data.*** Health data access bodies shall provide ***for an accessible and easily understandable opt-out mechanism, whereby natural persons must be offered the possibility to explicitly express their wish not to have all or part of their personal*** electronic health data ***processed for some or all secondary use purposes. In situation where natural persons explicitly express their wish to use opt-out mechanism to data holders, data holders shall direct natural persons to the health data access bodies.***	It may be useful to add wording along the line of 'where practicable' to allow for an appropriate level of flexibility because the opt-out cannot be made available retroactively for all data and in all contexts.
Amendment 85, Article 34(1) Health data access bodies shall only provide access to electronic health data referred to in Article 33 ***to a health data user*** where the processing ***of the data*** by the applicant ***is necessary for one of the following purposes, and in accordance with Article 6(1)(c) and Article 9(2)(g), (h), (i) and (j) of Regulation (EU) 2016/679***:	This article seems to suggests that all data processed under EHDS have to be compliant with GDPR – this is not currently the case with anonymised data. EHDS can provide the legal basis under GDPR, but all data processed under EHDS doesn't necessarily fall under GDPR.
Amendment 88, Article 34(1)(d) (d) ***university and post-university*** teaching activities in health or care sectors;	We would suggest to add 'Continuing Professional Development' or 'Life Long Learning' activities here, as healthcare professionals will participate in various training and education activities throughout their career (including congresses, courses, webinars provided my medical societies), and it may be beneficial to recognise the value of EHDS in contributing to these activities.
Amendment 111, Article 39 (1)(a) (new) ***Information on clinical trials shall not be included in the report until the clinical trials have been fully completed.***	We are unsure about the practical effects of this addition and what happens to trials that are terminated early because of negative safety or effectiveness aspects. It should be clarified if they are also considered fully completed because they have been closed formally

Amendment 113, Article 42(4) 4. Any fees charged to data users pursuant to this Article by the health data access bodies or data holders shall be transparent and proportionate to the cost of collecting and making electronic health data available for secondary use, objectively justified and shall not restrict competition. The support received by the data holder from donations, public national or Union funds, to set up, develop or update tat dataset shall be excluded from this calculation. The specific interests and needs of SMEs, public bodies, Union institutions, bodies, offices and agencies involved in research, health policy or analysis, educational institutions and healthcare providers shall be taken into account when setting the fees, by reducing those fees ***according to a predefined percentage of deduction based on the importance of the research to the society and the level of sensitivity of data requested and thus implied technical obligations to ensure maximum personal data protection.***	We believe the original European Commission text is more appropriate as it better supports the interests of SME's and academic or small research entities. The text should thus be: …by reducing those fees ***proportionately to their size or budget***.

Biomedical Alliance in Europe

Additional amendments proposed by BioMed Alliance

Additional amendments proposed by BioMed Alliance that we think should be added to the ENVI-LIBE Report:

Amendment	Proposed changes	Explanation
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

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	**Article 54 – Paragraph 2**	**Justification**

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.	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.**	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 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.** (xiv) incentives policy for promoting data quality and interoperability improvement;	**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 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 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.

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.