

---

**SPANISH BIOETHICS  
COMMITTEE REPORT ON  
ASPECTS OF SECONDARY USE  
OF DATA AND THE EUROPEAN  
DATA PROTECTION SPACE**

---

**2023**

## **REPORT OF THE SPANISH BIOETHICS COMMITTEE ON ASPECTS OF SECONDARY USE OF DATA AND THE EUROPEAN DATA PROTECTION SPACE**

### **Members of the Committee**

Ms Leonor Ruiz Sicilia (President)

Mr Juan Carlos Siurana Aparisi (Vice-President)

Ms María Desirée Alemán Segura

Ms Carme Borrell i Thio

Ms Atia Cortés Martínez

Mr Iñigo de Miguel Berain

Ms Lydia Feito Grande

Ms Cecilia Gómez-Salvago Sánchez

Mr Aurelio Luna Maldonado

Mr Alberto Palomar Olmeda

Ms Isolina Riaño Galán

Mr José Antonio Seoane Rodríguez

Ms Noa Laguna Goya (Secretary)

This report responds to the consultation of the State Secretariat for Health of the Ministry of Health on May 26, 2023, on some aspects of secondary use of data and the European data protection space.

Once the consultation had been received, the Committee adopted the following report at its plenary meeting on November 7, 2023, in accordance with Article 78 (1) (a) of Law 14/2007, of July 3, on biomedical research, which establishes, among the Committee's functions, reports, proposals, and recommendations for public authorities at the national and Autonomous Community levels on matters with relevant bioethical implications.

## INDEX

LIST OF ABBREVIATIONS, ACRONYMS AND ACRONYMS .....	4
1. INTRODUCTION .....	5
2. CONSULTATION .....	7
(A) Data types for secondary use (e.g. genomics) and possible limitations on their use .....	7
(B) The delimitation of prohibited uses, related to the types of data and also to the type of organisations requesting them.....	12
(C) The appropriateness of a prior ethical assessment of data access requests and the harmonisation of this function at European level .....	15
D) How to incorporate ethical assessment in data access bodies .....	18
(E) Possible obligations of data users with regard to the results obtained .	20
3. SOURCE DOCUMENTS .....	21

## LIST OF ABBREVIATIONS, ACRONYMS AND ACRONYMS

<b>AEMPS</b>	Spanish Agency for Medicines and Medical Devices
<b>Art.</b>	Article
<b>CBE</b>	Spanish Bioethics Committee
<b>ACs</b>	Autonomous Communities
<b>covid-19</b>	Coronavirus disease 2019
<b>LOPDyGDD</b>	Organic Law 3/2018, of 5 December 2003, on the protection of personal data and guarantee of digital rights
<b>DPD</b>	Data Protection Officer
<b>EDPB</b>	European data protection Board
<b>EDPS</b>	European Data Protection Supervisor
<b>EHDS</b>	European Health Data Space Regulation
<b>EIPD</b>	Impact Assessment
<b>AI</b>	Artificial Intelligence
<b>DGA</b>	Data Governance Act, 30 May 2022
<b>GDPR</b>	General Data Protection Regulation (Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC)
<b>EU</b>	European Union

## 1. INTRODUCTION

The Spanish Bioethics Committee provided an overall reflection on the opportunities and risks arising from the advancement of biology and technology to improve individual health in its report on the legal requirements for research on health data and biological samples in the context of the COVID-19 pandemic (April 28, 2020). The Committee also stated the appropriateness and lawfulness of the secondary use of health data and biological samples under such circumstances.

After that, on June 5, 2023, the Spanish Bioethics Committee released a report on the moral and legal effects of including additional information about "desired name" and "gender meaning" in the National Health System Protected Population Database. The report described the conditions for the lawfulness of this kind of processing of personal data and how to make sure that the secondary use of personal health data was lawful (see Articles 6 and 9 GDPR). In this report, the Committee also underlined the importance of respecting the principles relating to processing (Article 5 GDPR): the principle of lawfulness, fairness and transparency (Article 5.1 (a) GDPR), the principle of purpose limitation (Article 5.1 (b) GDPR), the principles of data minimisation (Article 5.1 (c) GDPR) and accuracy (Article 5.1 (d) GDPR) and the principle of integrity and confidentiality (Article 5.1 (f) GDPR).

Therefore, the lawfulness, appropriateness and correctness of secondary use ('further processing' in the GDPR expression: Articles 5.1 (b), 6.4 (a) and 89.1 GDPR) of health data is guaranteed, provided that certain conditions, which are the result of an adjustment of the different values and rights involved, are met. On the one hand, autonomy, information and decision-making, and privacy of the data subject; on the other hand, knowledge, freedom of research and public or collective health. Of course, these are not the only values and rights involved. People also have the right to self-determination over the data themselves, the integrity, confidentiality and security of personal information, on the one hand; and justice, solidarity, trust and the common good, on the other. All of them shall be protected.

The main argument in favour of the lawfulness and correctness of secondary uses – or extreme treatments – of health data is not based on an instrumental or pragmatic reason: the impotence of the autonomy of the data subject as a means of guaranteeing the protection of his or her values and rights; nor is it for a conceptual or theoretical reason: the inadequacy of individualistic conceptions of that autonomy. Although these reasons are relevant, the rationale is a real ethical reason: the importance of the values and rights at stake, the cooperative nature of community life and the methodological requirement to protect and harmonise these values through collective and, as such, community and cooperative deliberation.

This report responds to the consultation of the State Secretariat for Health of the Ministry of Health of 26 May 2023 on some aspects of secondary use of data and the European data protection space which have been translated into five issues. The report has allowed the Spanish Bioethics Committee to deepen and develop previous arguments by applying them to the context of the consultation. Most of the replies come from the interpretation and evaluation of EU and national legislation in Spain, which is currently the most precise legal outcome of the aforementioned deliberation.

**It is very important, in any event, to stress that this report has been drawn up on the basis of the proposal for EHDS presented by the European Commission. This proposal will be subject to changes throughout the negotiations with the Council of the EU and the European Parliament. Therefore, much of what we claim now can and should be properly qualified in light of the final text of the Regulation, when it is adopted.**

## 2. CONSULTATION

### (A) Data types for secondary use (e.g. genomics) and possible limitations on their use

#### 1. *Types of data*

The Proposal for a Regulation on the European Health Data Space (EHDS)<sup>1</sup> refers to ‘electronic health data’ as its subject matter. It should be clarified that ‘data’ means ‘any digital representation of acts, facts or information, as well as their collection, including as a sound, visual or audiovisual recording’ (Article 2 (1) of the Data Governance Regulation (DGA<sup>2</sup>), also in line with Article 2.1 of the Data Act<sup>3</sup>). Within this wide range, the EHDS also includes both personal and non-personal health data, as defined in Article 2.2 of the EHDS:

- (a) ‘personal electronic health data’ means: data concerning health and genetic data, as defined in Regulation (EU) 2016/679, as well as data relating to determinants of health, or data processed in connection with the provision of health services, which are processed in electronic form;
- (b) ‘non-personal electronic health data’ means: data concerning health and genetic data in electronic form that do not fall under the definition of personal data laid down in Article 4(1) of Regulation (EU) 2016/679.

Therefore, in principle, all types of personal and non-personal data concerning health and genetic data can be processed, although under the EHDS only secondary use is intended for the achievement of the purposes set out in Chapter IV of the Regulation (Art. 2.2 (e) EHDS). However, this – extended – definition of secondary use does not seem to be

---

<sup>1</sup> Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space.

<sup>2</sup> Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act).

<sup>3</sup> Proposal for a Regulation of the European Parliament and of the Council on harmonised rules on fair access to and use of data (Data Act)



directly compatible with what the General Data Protection Regulation (GDPR)<sup>4</sup> calls ‘further processing of data’ (the GDPR does not include the idea of ‘secondary uses’), as pointed out in point 42 of the Joint Opinion of the EDPB and the EDPS in this regard<sup>5</sup>. It will therefore be necessary to see how the two rules are reconciled.

Based on these general lines, it must be kept in mind that Article 33 of the EHDS includes a list of data that may be used for secondary use, stating that ‘data holders shall make available the following categories of electronic data for secondary use in accordance with the provisions of this chapter:

- (a) electronic health records;
- (b) health related social, environmental and behavioural determinants;
- (c) relevant pathogen genomic data, impacting on human health;
- (d) health-related administrative data, including claims and reimbursement data;
- (e) human genetic, genomic and proteomic data;
- (f) person generated electronic health data, including medical devices, wellness applications or other digital health applications;
- (g) identification data related to health professionals involved in the treatment of a natural person;
- (h) population wide health data registries (public health registries);
- (i) electronic health data from medical registries for specific diseases;
- (j) electronic health data from clinical trials;
- (k) electronic health data from medical devices and from registries for medicinal products and medical devices;
- (l) research cohorts, questionnaires and surveys related to health;
- (m) electronic health data from biobanks and dedicated databases;

---

<sup>4</sup> Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)

<sup>5</sup> [https://edpb.europa.eu/our-work-tools/our-documents/edpb-edps-joint-opinion/edpb-edps-joint-opinion-032022-proposal\\_en](https://edpb.europa.eu/our-work-tools/our-documents/edpb-edps-joint-opinion/edpb-edps-joint-opinion-032022-proposal_en)

(n) electronic data related to insurance status, professional status, education, lifestyle, wellness and behaviour data relevant to health;

(o) improved electronic health data (correction, annotation or enrichment of the data) that have been received by the data holder after processing as a result of a data permit.’

Therefore, the sources from which the data can be obtained and the type of data concerned are very broad. It should be noted, however, that the Proposal provides for an exception to this rule: data holders that qualify as micro-enterprises as defined in Article 2 of the Annex to Commission Recommendation 2003/361/EC (enterprises employing fewer than 10 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 2 million<sup>6</sup>) are not required to make their data available for secondary use (Art. 33.2 EHDS).

One question that may rise doubts is whether data that are determinants of our state of health – the neighbourhood in which we live, our profession, lifestyle, etc, should also be considered health data. In this case, while the GDPR do not say anything about, the EHDS does consider it to be health data, in accordance with Article 33(n), albeit separately from data that are directly indicative of health.

The EHDS, on the other hand, does not mention biometric data in this section, even though some of them may provide information on a person’s health. Nor does it explicitly mention data from research in general, i.e. ‘documents in digital form, other than scientific publications, collected or produced in the course of scientific research activities and used as evidence in the research process, or commonly accepted in the research community as necessary to validate research findings and results’ (Article 2.9 of Directive 2019/1024 on open data<sup>7</sup>).

This seems to contravene Article 10 (1) of the same Directive with regard to ‘open access policies’, which states that ‘Member States shall support the availability of research data by adopting national policies and relevant actions aimed at making publicly funded

---

<sup>6</sup> Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003), Article 2 (3).

<sup>7</sup> Directive (EU) 2019/1024 of the European Parliament and of the Council of 20 June 2019 on open data and the re-use of public sector information.

research data fully accessible'. It could be understood, in this regard, that such data could be included in the catalogue presented under Article 33 (8) EHDS, if we consider that there is a justification for doing so on the basis of the national legislation or voluntary cooperation with relevant data holders at the national level, in particular electronic health data held by private entities in the health sector, which would indicate that the list transcribed is not necessarily a closed list of data sources, but others may be included.

There are, finally, two considerations to keep in mind. First, the European Commission will be empowered to adopt delegated acts to amend the list to adapt it to the evolution of available electronic health data. Secondly, intellectual property rights to the data will not allow those who have them to avoid processing for secondary uses, although 'where such data is made available for secondary use, all necessary measures shall be taken to preserve the confidentiality of intellectual property rights and trade secrets' (Article 33 (4) EHDS).

## *2. Limitations on their use*

Limitations to the use of data are, in principle, marked by the rules governing the processing of personal data in general, as determined by the GDPR and the Data Protection and Digital Rights Guarantee Act (LOPDyGDD)<sup>8</sup>. In order to process them, it will always be necessary to find an exception to the general veto on the processing of data of special categories (in so far as they are health and genetic data) included in Article 9.1 of the GDPR and also a basis for lawful processing among those included in Article 6 of the GDPR. In the case of our legal system, the provisions of the 17th Additional Provision of the LOPDyGDD should also be complied with.

In order to be able to make secondary use of the data, the controller must, in any case, start by demonstrating that the purpose of the use falls within the purposes described in Article 34 (1) of the EHDS, namely:

- a) activities for reasons of public interest in the area of public and occupational health, such as protection against serious cross-border threats to health, public

---

<sup>8</sup> Organic Law 3/2018 of 5 December 2018 on the protection of personal data and the guarantee of digital rights.

- health surveillance or ensuring high levels of quality and safety of healthcare and of medicinal products or medical devices;
- b) supporting public sector bodies or EU institutions, bodies, offices and agencies, including regulatory authorities, in the health or care sector in carrying out the tasks defined in their mandates;
  - c) the production of official national, multi-country and EU statistics relating to the health or care sector;
  - d) education or teaching activities in health or care sectors;
  - e) scientific research related to health or care sectors;
  - f) development and innovation activities for products or services contributing to public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices;
  - g) training, testing and evaluating of algorithms, including in medical devices, AI systems and digital health applications, contributing to the public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices;
  - h) providing personalised healthcare consisting of assessing, maintaining or restoring the state of health of natural persons, based on the health data of other natural persons.

In addition, the data cannot be used for the purposes referred to in Article 35 EHDS, which expressly prohibits access to and processing of electronic health data obtained through a data permit issued in accordance with Article 46 EHDS where the purpose is:

- (a) taking decisions detrimental to a natural person based on their electronic health data; in order to qualify as “decisions”, they must produce legal effects or similarly significantly affect those natural persons;
- (b) taking decisions in relation to a natural person or groups of natural persons to exclude them from the benefit of an insurance contract or to modify their contributions and insurance premiums;
- (c) advertising or marketing activities towards health professionals, organisations in health or natural persons;

(d) provide access to electronic health data to third parties not mentioned in the data permit, or otherwise make them available;

(e) developing products or services that may harm individuals and societies at large, including, but not limited to illicit drugs, alcoholic beverages, tobacco products, or goods or services which are designed or modified in such a way that they contravene public order or morality.

## **(B) The delimitation of prohibited uses, related to the types of data and also to the type of organisations requesting them**

### *1. Delimitation of prohibited uses*

In order to be able to make secondary use of the data, the controller has to start by demonstrating that the purpose of the use falls within the purposes described in Article 34.1 EHDS and, in addition, not to use it for the purposes prohibited by Article 35 EHDS. (See paragraph A.2 *above*).

## *2. Limitations on treatment in relation to requesting organisations*

Article 47 of the EHDS expressly states: ‘Any natural or legal person may submit a request for data for the purposes referred to in Article 34.’ Therefore, there appear to be no *prima facie* general restrictions. However, recital (51) clarifies that “[w]here the resources of health data access bodies are limited, they may apply prioritisation rules, for example by giving priority to public institutions over private entities, but should not discriminate between national organisations or organisations from other Member States within the same priority category.” Therefore, it could be thought that, in case of scarce resources, access bodies may limit the processing of data, excluding at least temporarily some entities.

In addition, for the secondary uses described in points (a), (b) and (c), the EHDS specifies that access to electronic health data “shall only be granted to public sector bodies and Union institutions, bodies, offices and agencies performing the tasks conferred on them by Union or national law, including where the processing of data to carry out those tasks is entrusted to a third party on behalf of that public sector body or Union institutions, bodies, offices and agencies” (Art. 34.2 EHDS).

## *3. Special reference to secondary use for scientific research related to the health or health-care sector*

Beyond this restriction, the EHDS does not dictate other limitations on bodies, institutions or entities that can access data for secondary use. However, it is worth clarifying the uses related to scientific research related to the health or care sector (Art. 34.1 (e) EHDS).

The fundamental question is to determine which concept of research governs whether or not to authorise secondary use of data. This is an issue that raises conflicting views: from a very narrow view, which only defines as research the type of action that is aimed at reaching purposes that do not include the commercial exploitation of its result; to very broad interpretations that allow certain secondary uses of data held by biobanks for, *inter alia*, statistical purposes, the management and supervision of authorities, planning and reporting by authorities, teaching and knowledge management to be considered

“research” (Article 2 of the Finnish Law on the secondary use of health data and health and social data).

However, the position of the European Data Protection Board (EDPB) is that the term cannot be extended beyond its common meaning. Thus, it understands that “scientific research” in this context means “a research project developed in accordance with relevant sectoral methodological and ethical standards, in accordance with good practice”.<sup>9</sup> Therefore, the key question to be taken into account by the access bodies established by the EHDS is whether or not the research to be carried out complies with those basic requirements; if that is the case, the nature of the data user should not in itself determine the decision to be taken.

#### *4. Limitations on processing and type of data*

The material scope of the EHDS includes a very wide range of health and genetic data typologies and therefore, in principle, covers the processing of virtually all types of data. A different issue, however, is whether access to the data should be preceded by anonymisation, as in fact the regulation states that “health data access bodies shall make electronic health data available in an anonymised format, where the purpose of the processing by the data user can be achieved with such data, taking into account the information provided by the data user” (Art. 44.2 EHDS). Only where it is impossible to achieve the intended purpose with anonymised data the access bodies will provide access to the data in pseudonymised format. In this scenario, the information necessary to reverse pseudonymisation shall only be available to the health data access body (Art. 44.3 EHDS). Under no circumstances does the EHDS provide for access to data that has not been anonymised or pseudonymised.

It should also be recalled that the EHDS requires data processing to be minimised (Article 44 EHDS), in line with the corresponding principle laid down in the GDPR (Article 5.1 (c) GDPR). And, in any case, the EHDS provides for the necessary implementation of appropriate safeguards to ensure that the rights and interests of those affected are treated

---

<sup>9</sup> CF. Guidelines on Consent under Regulation 2016/679 of the former Article 29 Working-Party from 10.4.2018, WP259 rev.01, 17EN, page 27 (endorsed by the EDPB). At [https://ec.europa.eu/newsroom/article29/item-detail.cfm?item\\_id=623051](https://ec.europa.eu/newsroom/article29/item-detail.cfm?item_id=623051).

appropriately (for all, Articles 38 and 45 EHDS), including the need for processing to be carried out in a secure environment (Article 50 EHDS).

### **(C) The appropriateness of a prior ethical assessment of data access requests and the harmonisation of this function at European level**

The process of granting data permits necessarily incorporates an assessment of requests which will have an aspect that could be qualified as ethical, as it encompasses aspects traditionally evaluated by the Research Ethics Committees: the basis for standing, the safeguards put in place, respect for data subjects' rights, etc. In our view, this assessment should be carried out by a committee that would include people with knowledge of the ethics of data processing.

In addition, in many cases, the processing of data under consideration will require an Impact Assessment (EIPD), in accordance with Article 35 (1) of the GDPR. It shall always be borne by the controller, who assumes the responsibilities arising from its execution and the results it produces. Since the access bodies will be considered responsible for processing that allow access to the data, their role will be essential in this regard. In addition, the Data Protection Delegates (DPD) will obviously be able to provide the advice requested on the data protection impact assessment and monitor its implementation, which falls within their tasks (Art. 39.1 (c) GDPR).

It is therefore reasonable to assume that access bodies will necessarily carry out an assessment of the applications, including an ethical aspect. It would therefore be wise to ensure ethical advice to these bodies, which should be properly coordinated with the advice provided by DPDs in strictly compliance with data protection rules. In our view, including the DPD itself within the Committee to advise on the granting of the permit would be a relevant solution.

However, the decision to place the responsibility for ethical oversight on access bodies has at least two loopholes:



- In cases where a user requests access to the data of a particular data holder based in a Member State, the request may be made directly to that data holder, who will decide whether or not to grant access to the data, without the prior involvement of the access body which, in such cases, will be responsible for including this information in its annual report and for complying with its obligations under Article 37(1) and Article 39 (Article 49.4 EHDS).
- In cases where the user belongs to the public sector, it is not necessary to obtain the data permit (Article 46 EHDS), so supervision may be less restrictive.

#### *Harmonisation of ethical assessment at European level*

The essential body to ensure this harmonisation will in any case be the European Health Data Space Board (EHDS Board: art. 64 EDDS), whose essential function will be to facilitate cooperation and exchange of information between Member States. The specification of this function in the case of secondary data uses is laid down in Article 65.2 EDDS and includes the following tasks:

- (a) to assist Member States in coordinating practices of health data access bodies in the implementation of provisions set out in Chapters IV, to ensure a consistent application of this Regulation;
- (b) provide written contributions and exchange best practices on issues related to the coordination of the application at Member State level of this Regulation and of the delegated and implementing acts adopted on the basis thereof, in particular as regards:
  - (I) the implementation of the rules on access to electronic health data;
  - (II) existing technical specifications or standards relating to the requirements set out in Chapter IV;
  - (III) incentive policy to promote data quality and improved interoperability;
  - (IV) policies on fees to be charged by health data access bodies and data holders;
  - (V) the establishment and application of penalties;

- (VI) other aspects of secondary use of electronic health data;
- (c) to facilitate cooperation between health data access bodies through capacity-building, establishing the structure for annual activity reporting, peer-review of annual activity reports and exchange of information;
- (d) to share information concerning risks and data protection incidents related to secondary use of electronic health data, as well as their handling;
- (e) contribute to the work of the European Data Innovation Board to be established in accordance with Article 29 of Regulation [...] [Data Governance Act, COM (2020) 767 final];
- (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.

Harmonisation will therefore be carried out by the EHDS Board, building on the action of the access bodies. Article 37 (1) EHDS includes among the functions of access bodies (and contact points are by definition), to cooperate at national and EU level to establish appropriate measures and requirements to access electronic health data in a secure processing environment (Art. 37.1 (m) EHDS) and to cooperate at national and EU level and to advise the European Commission on techniques and best practices for the use and management of electronic health data (Art. 37.1 (n) EHDS).

Furthermore, it should be borne in mind that the annual reports of the access bodies will be transmitted to the European Commission (Article 39 EHDS), so it seems that harmonisation can benefit from a comparative analysis of the main difficulties and discrepancies observed in the performance of their tasks by these bodies. In order to harmonise this function at the European level, the EHDS has explicitly established a common standardised process for issuing data permits, with similar applications in different Member States, which will in principle ensure that all health data access bodies issue permits in a similar way. The process requires the applicant to provide the health data access bodies with several elements of information to help them assess the application and decide whether the applicant can receive a data permit for secondary data use, while also ensuring consistency between different health data access bodies. Such

information includes: the legal basis under Regulation (EU) 2016/679 for requesting access to the data (exercise of a public interest task assigned by law or legitimate interest), the purposes for which the data would be used, the description of the necessary data and possible data sources, a description of the tools necessary to process the data, as well as the characteristics of the secure environment that are needed (Recital 50 EHDS).

However, it will have to be seen in detail how criteria are harmonised between the different access bodies, which may also be one or more in each Member State. Both recitals 50 and 51 state that “in order to ensure a harmonised approach among health data access bodies, the Commission should support the harmonisation of data request as well as data request”. Article 53 (3) EHDS specifies that “[t]he Commission may, by means of implementing acts, adopt the necessary rules to facilitate the processing of DatosSalud@UE data access *requests*, including a common application form, a common data permit template, standard forms for common contractual electronic health data access arrangements and common procedures for handling cross-border requests, in accordance with Articles 45, 46, 47 and 48.’ Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2) EHDS, that is, with the assistance of a committee within the meaning of Regulation (EU) No 182/2011, composed of representatives of the Member States and chaired by the European Commission.

## **D) How to incorporate ethical assessment in data access bodies**

The EHDS states that access bodies may request an ethical assessment under the national law of data requests when data is requested in pseudonymised format, in which case the data applicant must in any case explain why it is necessary and why anonymous data would not be sufficient (Recital 50 EHDS). We consider that the intervention of a body aimed at providing ethical advice relating to the intended purpose of the processing would be extremely relevant. It is not the same, to give some examples, that we are dealing with a secondary use of data for the production of official national, multi-country and EU

statistics relating to the health or care sector, education or teaching activities in the health or health-care sector or scientific research related to the health or health-care sector.

The assessment to be carried out by the access body shall in any case benefit from the provision included in Article 45.4 of the EHDS: ‘Where the applicant intends to access personal electronic health data in pseudonymised format, the following additional information shall be provided together with the data access application: (a) a description of how the processing would comply with Article 6(1) of Regulation (EU) 2016/679; (b) information on the assessment of ethical aspects of the processing, where applicable and in accordance with national law’.

It must therefore be the user himself who provides the necessary information on the ethical aspects of the processing, albeit always on the basis of the provisions of the national legislation governing the processing. In that regard, it must be borne in mind that there may be substantial differences between the users of the data and the intended purposes. Thus, when the data is to be used for scientific research purposes, it will be necessary for the user to have the approval of a Research Ethical Committee, which should be responsible for validating it from an ethical point of view. Similarly, in the case of activities involving the development of medical devices or medicinal products, the involvement of the Spanish Agency for Medicines and Medical Devices (AEMPS) and the Committees of Ethics for Research with Medicinal Products will also be required, while in the case of training, testing and evaluation of algorithms, also for medical devices, in almost all cases (the exception is some of the class I ones), notified bodies would be incorporated into the equation, in accordance with the provisions of the Regulation on Medical Devices.

In short, some of the intended purposes have their own ethical evaluation system, which should ensure adequate protection of the rights and interests of those affected. In addition, access bodies will carry out audits of data users to ensure compliance of the processing with the EHDS, the results of which will be included in their annual reports, providing them with a monitoring mechanism of particular importance. It would probably be reasonable for access bodies to pay particular attention to data uses for purposes that do not incorporate such regulated intervention by institutions linked to the ethical monitoring of data processing.

In any case, it seems reasonable, in the opinion of this Committee, for access bodies to have adequate ethical advice, probably by adding ethics experts to the committees advising the body on granting data permit authorisation to users who have requested or not, in addition to the presence of DPDs.

### **(E) Possible obligations of data users with regard to the results obtained**

These obligations are described in Article 46 (11) and (12) of the EHDS:

11. Data users shall make public the results or output of the secondary use of electronic health data, including information relevant for the provision of healthcare, no later than 18 months after the completion of the electronic health data processing or after having received the answer to the data request referred to in Article 47. Those results or output shall only contain anonymised data. The data user shall inform the health data access bodies from which a data permit was obtained and support them to make the information public on health data access bodies' websites. Whenever the data users have used electronic health data in accordance with this Chapter, they shall acknowledge the electronic health data sources and the fact that electronic health data has been obtained in the context of the EHDS.

12. Data users shall inform the health data access body of any clinically significant findings that may influence the health status of the natural persons whose data are included in the dataset.

### 3. SOURCE DOCUMENTS

- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.
- Directive (EU) 2019/1024 of the European Parliament and of the Council of 20 June 2019 on open data and the re-use of public sector information.
- Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space. COM (2022) 197 final 2022/0140 (COD).
- Proposal for a Regulation of the European Parliament and of the Council on harmonised rules on fair access to and use of data (Data Act).
- Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act).
- Organic Law 3/2018, of 5 December 2003, on data protection and ensuring digital rights.