



## **OPEN DEI contribution to the feedback on the Data Governance Act**

The content of this document is based on inputs received from the Health & Care Large Scale Pilots cluster which has been initiated in December 2019. It is today composed of 9 Large Scale Pilots which aim to improve health and quality of life of patients with the support of innovative technologies.

This cluster creates concrete synergies between the Large-Scale Pilots and facilitates transfer of experience and knowledge, extending thus the concept of co-creation and eco-system. In its role of ambassador of the healthcare sector in the [OPEN DEI](#) project, EHTEL is furthermore contributing to establish bi-directional links between the healthcare domain and the three other domains (manufacturing, energy and agri-food), exploring thus further the possibility to create more links between sectors

### **Legislative coordination**

The DGA will be another important piece of European legislation intervening in an already complex puzzle. The GDPR governs the collection, processing and use of personal data, there is a Regulation on the free-flow of non-personal data, the Open Data Directive which already supports the re-use of public sector datasets, and the Database directive. The four pillars of the DGA deserve important scrutiny from the perspective of the actors involved in the e-health ecosystem: the re-use of sensitive public sector data; corporate and individual data altruism, fostering coordination and interoperability through the European Data Innovation Board.

**OPEN DEI, representing a cluster of EU funded projects and large-scale pilots, welcomes the DGA and proposes the following recommendations co-authored by the projects. These are explained more fully in the accompanying PDF.**

### **Observations**

- One question relevant for the e-health ecosystem concerns the governance framework to promote confidence in data sharing between organizations and foster

the development of EU data spaces. In this context we should **probably further develop and analyse the role of data intermediaries in the e-health context and work on possible label/certification** of their role and functions

We welcome the proposed role of the data intermediary, but recommend that the permitted roles in the content of eHealth are worked out in more detail, with a view to labelling/certification.

The territorial scope of the DGA has to be further clarified and also the role and liability of EU-based representatives.

- In the context of the European Union, hospitals and other health and e-health actors have different legal personalities. **The measures on the re-use of public data will be applicable to public sector bodies defined as “State, regional or local authorities, bodies governed by public law or associations formed by one or more such authorities or one or more such bodies governed by public law”.** We probably need to fully assess the implication of the provisions on hospitals governed by public law. For instance, the DGA could also promote data provisioning by non-public entities that, nevertheless, provide public services (for example, private not for profit hospitals or third sector organisations providing social care and/or integrated care), given the huge differences between healthcare structure and actors in the different Member States.

The DGA specially applies to public sector bodies, which it defines. We recommend that the implications of extending the scope to non-public entities in health whose data is of great relevance and value e.g. private not for profit hospitals or third sector organisations providing social care or integrated care

- Further coordination is probably needed in the context of oversight and enforcement of the DGA, especially on the role and coordination of national authorities. Member States are in fact required to nominate a “competent authority” to monitor the compliance with the DGA. **Since the DGA applies also to personal data protected by the GDPR, this authority will act as an additional regulator in the field. Clarification of role and responsibilities is probably needed to this extent.**

We recommend greater clarity about the alignment of the national competent authorities undertaking DGA oversight and enforcement with the bodies performing that role for the GDPR.

- There is probably more clarification to be developed on the issue of consent. The proposal for a DGA specifically refers to the creation of data altruism consent forms. According to recital 36 “(...) **Data subjects in this respect would consent to specific**

**purposes of data processing, but could also consent to data processing in certain areas of research or parts of research projects as it is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection”**. According to the GDPR, however, consent needs to have certain specific characteristics. According to the EDPB “a service may involve multiple processing operations for more than one purpose” and in those cases “the data subjects should be free to choose which purpose they accept, rather than having to consent to a bundle of processing purposes”. The EDPB also explained: “if the controller has conflated several purposes for processing and has not attempted to seek separate consent for each purpose, there is a lack of freedom. **This granularity is closely related to the need of consent to be specific”**. It should probably be further assessed, in the context of data altruism, the granularity of this consent. Indeed, the scope of data altruism should be addressed by the **regulator in a set of cases in which the principle of altruism is either auspicious, appropriate or at least compatible**. Furthermore, the pre-definition of general cases for altruism will facilitate the creation of a common understanding of this specific prerogative of data subjects removing the risks concerning the proliferation of requests for data sharing and ‘ad hoc’ and bundling approaches which will result in an effective understanding of these requests and therefore of the expression of the right to share for common good. This option requires, though, a clear formulation and tight supervision from the regulator to avoid misuse or blind spots.

We welcome, as part of the implementation of data altruism, the introduction of data subject consent for areas of general interest including processing for scientific research purposes that cannot be precisely specified at the time of collecting the consent. However, greater clarity and guidance will be needed on how to remain compliant with the GDPR which requires consent to be specific. Clear and detailed guidance will be required for the public, data intermediaries, research users and regulators to ensure consistent pan-European interpretation and application, and to give confidence to all stakeholders.

- Health data might be used for research under wide consent formulas according to the art. 89 RGPD as long as national laws allows it specifically. In order to propose a harmonized regulation for wide consent on secondary use of health data, the Spanish implementation of art. 89 RGPD (Ley Organica 14/2018, Disposición Adicional 17) allows - health authorities and public institutions with powers in public health surveillance, to carry out scientific studies without the consent in situations of exceptional affectation to public health- data that have been obtained for a specific request, may be used for research purposes related to the original one- if pseudonymised health data may be used for research with approval of IRB.

The DGA should make clear the grounds on which data may be used for scientific research without requiring consent, and in particular if specified pseudonymisation safeguards would be deemed sufficient to permit such data use.

- A comprehensive revision of case law could be relevant in order to better identify the critical issues of health data governance. For instance, Padris+ Data analytics program for health research and innovation (Catalunya, Spain).
  - Description: Data analytics program for health research and innovation. The Data Analysis Program for Health Research and Innovation (PADRIS) has the mission of making available to the scientific community the related health data to promote research, innovation and evaluation in health through access to the reuse and crossing of health data generated by the comprehensive health system for public use of Catalonia (SISCAT), in accordance with the legal and regulatory framework, the ethical principles and transparency towards the citizens of the program. PADRIS is also an initiative to contribute to improving the position of Catalonia in the international arena as a reference territory in the information society that is moving towards a new country model specializing in high value-added services and that promotes research and innovation as an engine for improving the health of citizens and the competitiveness of their production model, as promoted by the strategies designed by the European Commission to reuse health data generated by public administrations to drive research and transfer its results in clinical practice.
  - Antecedents: Padris was preceded by VISC+ initiative which intended to deliver health data from electronic clinical records (circa 6M eCR) through a for profit platform. This initiative was rejected by the Catalan Parliament on various [basis](#) and the programme was rebuilt on altruistic public data donation basis.