



M8.3 Draft guideline for Health Data Access Bodies on informing natural persons about the use of health data – “Citizen Information Point”

TEHDAS2 – Second Joint Action Towards the European Health Data Space

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0 Document info

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1 Executive summary

In the scope of TEHDAS2¹ (the second joint action Towards the European Health Data Space), this guideline provides a detailed account of the information that health data access bodies (HDABs) must provide to natural persons about the secondary use of health as laid out in Article 58 of the European Health Data Space (EHDS) regulation². HDABs are responsible for providing easily accessible information on the conditions under which electronic health data are made available for secondary use, on rights concerning opt-out mechanisms, on processes concerning significant findings, and on the role and benefits of an HDAB.

This is done by means of a citizen information point (CIP). The term is introduced in this guideline in a very broad way: all natural persons are addressed, not only citizens in the technical sense, and although webportals are the obvious implementation choice other solutions might be thinkable.

After describing what a CIP is, the guideline focusses on three main aspects of information sharing: What, how and when is information provided?

The conditions under which electronic health data are made available for secondary use in EHDS include general information on the legal basis for granting access as well as the measures taken to protect the rights of natural persons and their rights regarding secondary data use per se. It also includes details on the entity that has been granted access to the data and for what purpose, alongside the results obtained by the health data user. Additional suggestions and examples for information that might be interesting to natural persons or that might increase citizens' awareness, trust and engagement are also included in the guideline.

All information provided through the CIP should be easily and digitally accessible at least in both the official national language(s) and English. The CIP should be designed in a way that addresses the needs of users both in terms of usability as well as the structure and detail of information provided.

Finally, the guideline provides detailed information on the timeline for publishing information starting with the immediate publication of health data requests and results to the publication of legal grounds as well as the updating of information no later than 30 working days after issuance of an access decision.

Information about significant findings, purposes of secondary data use as well as the coordination between HDABs are largely in the scope of other TEHDAS2 documents which are referred to in the guideline and thus will not be discussed in detail.

This guideline serves as operational guidance for HDABs describing all information obligations of HDABs towards natural persons regarding secondary use of electronic health data. In doing so, it ensures alignment with the EHDS regulation.

¹ Second Joint Action Towards the European Health Data Space – TEHDAS2, <https://tehdas.eu/>

² Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 (Text with EEA relevance), <https://eur-lex.europa.eu/eli/reg/2025/327/oj>

2 Introduction

2.1 Advancing health data use in the European Health Union

As part of the European Health Union³, the European Union (EU) is advancing the use of health data for secondary purposes, including research, innovation and policymaking. Smooth and secure access to data will drive the development of new treatments and medicines and optimise resource utilisation—all with the overarching goal of improving the health of citizens across Europe.

TEHDAS2, the second joint action Towards the European Health Data Space (EHDS), represents a significant step forward in this vision. The project will develop guidelines and technical specifications to facilitate smooth cross-border use of health data, and support data holders, data users and the new health data access bodies (HDABs) in fulfilling their responsibilities and obligations outlined in the EHDS regulation.

TEHDAS2 focuses on several critical aspects of health data use.

- Data discovery: findability and availability of health data, ensuring it is accessible for secondary purposes.
- Data access: developing harmonised access procedures and establishing standardised approaches for granting data access across Member States.
- Secure processing environment: defining technical specifications for environments where sensitive health data can be processed safely.
- Citizen-centric obligations: providing guidance on fulfilling obligations to citizens, such as communicating significant research findings that impact their health, informing them about research results and ensuring transparency in how their data is used.
- Collaboration models: developing guidance on collaboration and guidelines on fees and penalties as well as third country and international access to data.

TEHDAS2 will contribute to harmonised implementation of the EHDS regulation through the concrete guidelines and technical specifications. Some of these documents and resources will also provide input to implementing acts of the regulation. Hence, the joint action will increase the preparedness for the EHDS implementation and lead to better coordination of Member States' joint efforts towards the secondary use of health data, while also reducing fragmentation in policies and practices related to secondary use.

2.2 Purpose and context of this guideline

The main objective of this guideline is to enable the engagement of citizens with the EHDS regarding the secondary use of health data. This should be achieved through the instalment of citizen information points (CIP).

Therefore, this guideline supports HDABs in meeting their legal obligations regarding transparency, communication, and accessibility of information to natural persons under the EHDS regulation. It focuses on the means of delivery of information rather than the content of the information itself.

³ European Commission - European Health Union, Protecting our health together, https://commission.europa.eu/topics/public-health/european-health-union_en

2.3 Target audience

The target audiences of this guideline are:

- HDABs in their task of establishing “*an information system to comply with the obligations laid down in Article 58*” - the CIP - are the primary audience. It should provide them with useful information and actionable guidance. It cannot be a complete “handbook” or checklist that guarantees HDABs to cover everything they need to consider. But besides the mandatory aspects it analyses and explains, the guideline should also provide a good understanding of the extent and complexity of the HDAB’s task at hand and give valuable directions and recommendations that facilitate them to achieve a good result that really serves the citizens using it.
- The guideline cannot be written without always having the population at question, i.e., natural persons, and their needs in mind. For easier readability, this guideline uses the term citizens to refer to natural persons as laid down in Article 58. Any future CIP must serve their need for easily accessible and understandable (yet not over-simplified, superficial) information, providing transparency, creating trust and public value.

Therefore, each topic has a twofold question to answer:

How can guidance be formulated, so that it is useful for an HDAB to implement a CIP, that then is useful for the citizen?

This guideline will not specifically inform any of the upcoming Implementing and Delegated Acts. Nevertheless, the EHDS Board might take this guideline up, for example with respect to lay-language in translations or when harmonising communication about the implementation of the regulation across countries. Also, the Central Platform might consider the guideline.

This document should be understood as an expert opinion and guidance document developed within the TEHDAS2 framework, reflecting technical and expert input from the project partners. It is not legally binding and does not constitute a formal guideline or technical specification under the European Health Data Space.

This document does not represent the position of the European Commission.

Legally binding and enforceable requirements under the European Health Data Space are laid down in regulation (EU) 2025/327 and, where applicable, in implementing acts adopted by the European Commission, within the limits of the empowerments provided by the regulation.

3 What is an information point?

The CIP is a public information mechanism, accessible electronically, allowing HDABs to comply with the requirements of Article 58(1) of the EHDS regulation. It constitutes an information and accessibility interface designed to ensure that information on the conditions under which electronic health data are made available for secondary use is readily accessible. The CIP thereby supports the HDAB in fulfilling its transparency and accountability obligations.

Primarily intended for natural persons whose electronic health data may be used for secondary use, the CIP reflects the citizen-centred objective of Article 58 of the EHDS regulation. While these guidelines are addressed to HDABs, the CIP itself is designed to primarily serve the information needs of natural persons and the general public, as well as other stakeholders (such as healthcare professionals, policy, research, media, and education/students, compare [Annex 5 - Landscape analysis of health information portals](#) seeking transparent and reliable information on secondary use activities.

The CIP is an accessibility and information interface and does not constitute a decision-making body, operational data access management tool, or permit management system. It does not replace or perform the regulatory, authorisation, or supervisory functions entrusted to HDABs or other competent authorities.

Each HDAB is responsible for establishing, maintaining, and updating its own CIP for which one or all national HDABs are responsible with regard to the content to be provided. While the EHDS regulation allows the HDAB some discretion in how the CIP is implemented, it requires that the CIP covers, at a minimum, all information listed in Article 58(1), points (a) to (g), ranging from the legal basis for electronic health data access, rights of natural persons, HDAB identity and contact, to electronic health data access actually granted, whether through data permits or approved health data requests, and the results and outcomes of projects. The HDAB shall publish the information referred to in Article 58(1), as further specified in chapter 4 [“What information shall be provided?”](#).

Where a member state designates multiple HDABs it will be for the HDABs to define how they coordinate this work. It is encouraged, notwithstanding each HDAB’s individual obligation to maintain a CIP, to establish a “one-stop-shop” portal or a national CIP, managed by the coordinating HDAB appointed by the member State, to avoid fragmentation of information. Indeed, when a member state designates several HDABs, it must appoint one HDAB as coordinator, responsible for coordinating tasks with the contributing HDABs, both within its territory, as well as, where relevant, the HDAB or coordinator of the other member states involved, in accordance with Article 55(1). The coordinating HDAB must ensure the consolidation and public availability of all information in the national CIP, while the contributing HDABs must ensure the accuracy and completeness of the information within their scope and provide it to the coordinator, covering at least the minimum information required under Article 58.

The CIP forms part of the elements to be published by the HDAB under Article 57(1)(j)(vi) of the EHDS regulation (see chapter [4](#)). Its main purpose is to present the information required under Article 58(1) in a structured, clear, and easily searchable manner, ensuring it is readily accessible to natural persons (see chapter [6](#)). To that end, the CIP constitutes one component of the information system that collects, manages, and provides information on the secondary use of electronic health data, to comply with Article 58.

Each Member State is free to decide on the specific modalities for implementing the CIP. However, in practice, the information required under Article 58 could still be presented alongside the information and documents published under Article 57(1)(f). See chapter 6 [“How should the information be provided?”](#).

4 What information shall be provided?

Under the EHDS regulation, HDABs are required by Article 58 to make publicly available information on the conditions under which electronic health data are made available for secondary use. This obligation supports transparency by enabling natural persons to understand how, why, and on what basis their data may be used beyond primary care. Article 58(1) establishes a list of information that shall be provided, covering legal, technical, organisational and procedural aspects of secondary data use. Thereby, EHDS regulation aims at avoiding fragmentation among MS and create transparency and comparability for citizens between individual HDABs. Additional information may be provided (see chapter [5](#)).

The information provided should explain the right of natural persons to opt out from the secondary use of their personal electronic health data in accordance with Article 58(2), including the procedure for exercising this right where Member States allow it to be carried out through the HDAB. It should also explain the possibility that significant findings relevant to a natural person’s health may be communicated in accordance with Article 58(3). Finally, the information should clarify the role of the HDABs themselves as well their benefits, as provided for in Article 58(4).

The current landscape in which this norm intends to operate seems particularly fragmented at the national level (see [Annex 5 - Landscape analysis of health information portals](#)). Most of the observed national health data portals do not provide direct aggregated information for secondary use but rather offer user support through available channels. Therefore, Article 58 EHDS aims at providing transparency regarding the use of health data in a comprehensive way, avoiding fragmentation among Member States, and providing the necessary information to be made available for users.

4.1 Legal basis for granting access to electronic health data for health data users

HDABs shall publicly inform about the legal basis under which electronic health data is made available for secondary use. Electronic health data may only be made available for the secondary use purposes listed in Article 53(1), such as research, innovation, public health, and policymaking. Access under the EHDS is authorised through a formal administrative decision of the HDAB, either by issuing a data permit under Article 68 or approving a health data request under Article 69. This decision constitutes the legal basis for the health data user’s access and defines binding conditions, including the approved purpose, categories of data, duration of access, and safeguards that must be applied. Health data may only be used in accordance with these conditions.

4.2 Safeguards to protect the rights of natural persons

To ensure that health data are used safely and responsibly, the EHDS regulation requires HDABs and trusted data holders (TDHs) to implement technical and organisational measures when granting access for secondary use. These are:

Organisational measures

HDABs conduct thorough assessments of data access applications, ensuring compliance with legal and ethical requirements.

Regular training and periodic audits of SPEs should be implemented to ensure compliance with permit conditions and data protection requirements.

Data usage is only permitted for purposes expressly permitted by the EHDS, and secondary uses for purposes that are not explicitly approved in a data permit are prohibited.

Health data users must implement certain requirements, including complying with data permit conditions, ensuring data security and confidentiality, not attempting to re-identify individuals, and using the data only for the authorised purpose, as set out in Article 61.

Access by health data users from third countries are subject to additional requirements in accordance with Regulation (EU) 2016/679 (GDPR)⁴ Chapter V. If a Member State applies additional requirements related to international data transfers or safeguards under national law or applicable EU data protection rules, these should also be listed.

Technical measures

Secondary use of personal data is only allowed within a secure processing environment (SPE), where access is tightly controlled and processing operations monitored.

Only anonymised results can be downloaded from the SPE for the production of project results.

Data may only be kept for the duration of the approved project and are deleted thereafter, ensuring that sensitive data are not retained longer than necessary.

Together, these measures ensure that health data are processed in a safe, controlled manner that protects individual rights while enabling legitimate research and innovation. A short explanation what these terms and measures mean should be provided.

Data catalogues describing datasets according to Art. 55(1)(j)(i) and Art. 77 do not include personal data.

4.3 Rights of natural persons in relation to secondary use

HDABs shall provide clear information about the rights of natural persons in relation to secondary use and how they can be exercised. These are:

Right to opt out

Individuals have the right to opt out of having their data used for secondary purposes using the processes member states specify under Article 71, and HDABs must provide accessible information on how to submit an opt-out request and facilitate its implementation by providing adequate guidance.

⁴ 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) (Text with EEA relevance), <https://eur-lex.europa.eu/eli/reg/2016/679/oj>

Right to be informed

While the opt-out mechanism is the primary means through which individuals can exercise control over the secondary use of their health data, it does not displace other individual rights under Chapter III of GDPR. Rights such as the right to information and the right of access therefore remain applicable; however, care must be taken when providing individual-level information in response to such requests, to avoid re-identification risks within research or statistical datasets. In accordance with Recital 66 EHDS, the CIP is intended to complement existing transparency obligations under Article 14 GDPR. While it requires that individuals be informed when personal data are not obtained directly from them, Article 58 EHDS adds sector-specific transparency elements relating to the governance of secondary health data use. These include, for example, information on the technical and organisational safeguards applied, the identity and contact details of the HDAB, and the framework governing data access decisions — elements that may not be fully covered by general data protection notices. Where exceptions to the information obligation under Article 14(5) GDPR apply, the public information required under Article 58 EHDS helps ensure that individuals still achieve a minimum level of awareness regarding the secondary use of their electronic health data. The information provided under Article 58 should therefore be coordinated with the content of data permits and approved requests under Articles 68 and 69 EHDS, ensuring consistency between publicly available information and the legally binding conditions attached to data access.

Right to receive information about significant findings

Natural persons should be informed that secondary use of electronic health data may reveal health-relevant findings. In line with Article 58(3) EHDS, such findings may be communicated via the health data holder or a health professional, subject to applicable conditions and the individual’s right to opt out of being informed about such findings.

Right to lodge complaints

In addition, citizens can lodge complaints with the HDAB if they believe their rights are negatively affected or if data are being used inappropriately. In accordance with Article 81 EHDS easily accessible tools for the submission of complaints shall be provided, and the complainant shall be informed about progress and the decision taken.

4.4 How individuals can exercise their rights

The CIP shall provide information on how the rights regarding the secondary use of their data can be exercised by a citizen. Clear and easy instructions must be given how this is done. The CIP may also state that information on rights regarding data held in other EU Member States or by authorised participants, if applicable, must be found through the respective CIP.

HDABs must have arrangements in place to allow citizens to exercise their rights appropriately, which shall be in accordance with Chapter III of Regulation (EU) 2016/679 (GDPR - Rights of the data subject). Article 58 therefore mandates to inform about these arrangements in an accessible way.

Depending on the right exercised, different stakeholders may be in charge (e.g., the opt-out may differ from the exercising of data subjects’ rights under the GDPR). Electronic gateways may allow a particularly secure exercising of data subjects’ rights, but these should not be the only option.

Inclusiveness requires that also non-electronic possibilities must be implemented, which have to foresee their own communication channels and ways to authenticate the respective citizen.

The information provided by the CIP should make transparent to citizens that HDABs and other involved parties handle requests securely, transparently and in accordance with the data minimisation principle, that all safeguards required for data protection are maintained, that any actions are conducted in line with the conditions of the data permit, ensuring that data are only used for the purpose approved by the HDAB. These arrangements help citizens maintain oversight of how their health data are used and ensure that secondary use is conducted responsibly.

4.5 Identifying and contacting the relevant HDAB

At a minimum, the publicly available information should include the official name of the HDAB(s) and its primary contact channels. This typically includes the official postal address and electronic contact details (such as a dedicated email address or web contact form). Where appropriate and consistent with national administrative practice, additional contact channels, such as a telephone number, may also be provided.

4.6 Who has access to health data and for what purposes

HDABs must make publicly available information on who has been granted access to datasets of electronic health data, to which datasets they were granted access and for what purpose(s).

The HDAB must provide information on the health data user(s) and on the institution accessing the data, including the institution’s name, address, and contact details, as specified in the data permit. Data protection applies here, as well, therefore the balance of public information with data protection of health data users has to be considered carefully. Often, the intended purpose (e.g. research including publication of results) will imply the publication of the identity of a lead researcher. As relevant information (e.g. to allow searching for related publications) the HDAB might provide the name and affiliation of the lead researcher as disclosed on the data access application or the data access request. The regulation does not require disclosure of individual researchers’ identities and the HDAB should not publish the identities of individual research team members authorised to access data in the SPE beyond the lead researcher. In other cases (e.g. for a purpose related to public health) it might be more relevant to inform about the conducting organisational unit than the individual lead researcher. Information duties on “Who” has accessed data should extend to the organisation on behalf of whom the application is made. The public information should include whether the applicant is a natural or legal person, and in the case of the latter the characteristic of the organisation whether a public body, Union institution, NGO. Further, it should be stated where access to data is granted to a public body or Union institution for carrying out tasks enshrined in the mandate of the organisation.

Publication of information on “Which data” includes the datasets that are authorised to being accessed according to the data permit as well as the approved purposes of processing, and the duration of the authorised use.

Publication of information relating to the purpose for which access is granted should correspond to information contained in the data permit or response to a data access request. Specifically, it should

include both the relevant purpose(s) for processing referred to in EHDS Article 53(1) and the detailed description of the research objective.

4.7 What are the results obtained by the health data users

Health data users shall make public the results or output of their secondary use and to assist HDABs in making that information public in the CIP. To this end they should provide a lay summary of the results of their projects. The TEHDAS2 deliverable D8.4 *Guideline for data users on how to fulfil the duties regarding research outcomes* will provide details on what HDABs can expect from health data users, which is then to be used by HDABs to publicly inform via their CIPs.

5 What additional information can be provided?

Additional to the obligation as laid down in Article 58 for HDABs on what information shall be provided in their public information system for citizens, HDABs may provide further information based on national practices regarding information on health data, communication on research, health policy and national programmes.

Citizens’ awareness, trust and engagement

Providing information to the public could enhance citizens trust and engagement for sharing health data for secondary use, consequently contributing to the success of reaching the objectives of EHDS. The report from the TEHDAS Citizen Work Package⁵ presents recommendations by citizens on how they want their data to be used and on their desired role in the EHDS.

Additional to fulfilling its obligations towards natural persons as detailed in Article 58 for HDABs pursuant to Article 57(1) subparagraphs (f), (j)(vi) and (k), HDABs have the right to provide further non-obligatory information to individuals. Natural persons who have not exercised their right to opt out of the secondary use of their health data might be interested in more information on how their data has been used. Such additional information may include links to websites of research projects, graphs or videos to illustrate the findings, or links to other related resources. HDABs could highlight particularly impactful results obtained and compile feature reports beyond the customary lay summary provided on results.

EHDS interplay with other relevant EU legislation regarding secondary use of health data

The EHDS regulation aims to establish a collaborative ecosystem and an EU wide infrastructure where electronic health data can be accessed for secondary purposes. However, various ways or methods may exist in member states for re-using health data for purposes other than the purposes for which they were initially collected or generated. Countries already have mechanisms in place to carry out clinical trials or the collection of health data for designated purposes, and these mechanisms or systems are based on other relevant EU legislation than the EHDS regulation, e.g. GDPR or the Clinical Trials Regulation No 536/2014 (CTR)⁶.

The landscape analysis on existing health information portals (see [Annex 5 - Landscape analysis of health information portals](#)) confirmed that several entities already operate information points and provide at least basic information about conditions on use of personal health data. The information about secondary use of health data, which is based on legislation other than the EHDS regulation potentially differs from what is to be provided by HDABs acting in the EHDS.

While the EHDS provides a consistent and secure framework for secondary use of health data for a variety of purposes, systems for other purposes are maintained and will co-exist. It is very likely that HDABs will need to clarify or may receive questions from citizens about what is generally happening with their health data. In the interest of clarity and transparency, HDABs should firstly be aware of

⁵ TEHDAS - Deliverable 8.1, Qualitative study to assess citizens’ perception of sharing health data for secondary use and recommendations on how to engage citizens in the EHDS - 31 March 2023, <https://tehdas.eu/app/uploads/2023/03/tehdas-study-to-assess-citizens-perception-of-sharing-health-data-for-secondary-use.pdf>

⁶ Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance, <https://eur-lex.europa.eu/eli/reg/2014/536/oj>

such other mechanisms or systems and secondly be prepared to provide the necessary explanations without going into details of various cases outside the scope of the EHDS. Citizens should receive clear information that does not cast doubt or distrust in the EHDS. The scope of the CIP and of the HDAB as such should be unmistakable, as well as the relevance of secondary use under EHDS for and the distinction from the other health data processing mechanisms.

HDAB is also encouraged to collaborate with other authorised portals and entities in the country that provide information to citizens (individuals) regarding any re-use of health data, with the aim of promoting clarity and transparency in this area.

Enabling individual information

Citizens are likely interested to find out in a targeted way, which of the projects approved are using their data as this cannot be easily found from the public information. If the national (health) information system is already at advanced stages and there is a transparency tradition on data access in a member state to provide information to citizens at individual level, HDABs might consider using an existing portal for individual information where citizens could seek information specifically related to their personal health data.

Considering that the CIP defined in the EHDS regulation lays down obligations for providing information to all citizens, namely to the public, and that citizens are rather interested in how their individual health data are used, HDABs could demonstrate their responsibility for respecting individuals' rights by explaining how they ensure the application of the GDPR, especially focusing on Article 14. General information to all citizens might not meet their expectation related to individual's interest. It might generate frustration if there is no notification to individuals and they must search regularly through all projects to find out when, for what purposes and by whom their data might be used. Although there is no obligation under EHDS for such a notification, it may also be necessary to be offered following a data protection by design and default approach to Article 14 of the GDPR. Therefore, the option to provide information at individual level should be assessed by HDABs and discussed with the national supervisory authorities.

Providing health data user information

Article 58(1) provides what information shall be provided in the CIP regarding the data use project in the CIP. This information does not cover the full scope of information that is required in Article 14 of the GDPR. Effectively, the basic information provided is enough to subsequently let citizens whose data may be used in a project access the webpage of the health data user and find there the full information. To ease obtaining this information, it could be considered that the full information as required under the GDPR is made available for all data use projects in the CIP directly, therefore lowering the efforts citizens must undergo to find relevant information.

Patient communities, disease-specific information

Additional to the obligatory information via the CIP on secondary use of health data, information could be provided through patient communities, e.g. the European Patients' Forum. According to Article 84(2) on promoting and supporting digital health literacy and digital health access, awareness-raising campaigns and programmes shall be tailored to the needs of specific groups and shall be developed, reviewed and, where necessary, updated. HDABs could contribute to fulfilment of this obligation by communication to the targeted patient communities about the secondary use of the disease specific health data via the CIP and with seeking feedback from the patients' communities

on methods for providing information that could be useful for reviewing and updating the disease specific health campaigns and programs.

Educational features, eHealth awareness

Based on the already well-developed functionalities and practices of existing health information portals, CIPs might offer practical “how-to-use” guides, glossaries, interpretation of the terminology used, they could develop and maintain FAQs, publish news items or articles that contain useful public information.

Furthermore, the CIP should provide plain language guides on at least basic concepts such as: What is secondary use? How are permits granted? What are *datasets*? What does *publication* mean and what not (e.g. no individual tracking)?

To increase accessibility (compare chapter 6 also for first-time-users, the above-mentioned FAQs could be combined with a step-by-step description of the functionality, of the content and of the CIP’s use.

Via the CIPs HDABs could promote the citizens’ understanding and recognition of and activities for secondary use for the ‘public good’. This angle would feed the development and further improvement of the member states’ eHealth strategies and action plans.

6 How should the information be provided?

Accessibility

The CIP should include an accessibility statement, to ensure equal access for persons with disabilities and provide non-discriminatory digital access. The CIP should be available in official national language(s), include an English version for EU interoperability, and might consider additional language support where appropriate. The landscape analysis showed that while many existing portals are multi-lingual, providing at least English as second language is very common. An option could be to use European Commission’s AI translation services and EU language tools, with either a mandatory human review for legal accuracy or a disclaimer that it is an automatic translation and the HDAB is not responsible for its quality.

For accessibility it is essential that texts are understandable by readers with different knowledge and capacity. Therefore, not only the number of available languages is relevant, but also the careful use of terms and structure. CIPs should use lay language and simple language wherever possible and appropriate without compromising the content. More difficult or expert-level content should be summarised in the most accessible way possible.

Accessibility may also be a question of information integration into existing portals. This can not only create synergies, but it may also make the information retrieval for data subjects easier if their information is not distributed over too many different portals. Existing information and/or healthcare portals in the country could be considered. Existing portals predominantly address residents as the main audience, as well as HCPs in many instances or further stakeholders, but usually focusing on primary use. Therefore, CIPs should account for synergies as well as different needs in secondary use. Exemplary portals examined in the landscape analysis that show all these aspects have been seen from Spain and the Netherlands. HDABs should ensure that the information for citizens is objectively accessible.

The presentation layer should adopt a user-centred design approach, validated through testing with real users, and provide guided pathways to support citizens with limited digital skills in navigating and understanding the information. Any portal should also comply with established accessibility standards, ensuring inclusive access for all users, in particular by adhering to the Web Content Accessibility Guidelines (WCAG).

Structure

The CIP should be designed as a structured transparency infrastructure aligned with EHDS legal obligations, EU harmonisation requirements, accessibility standards, and long-term interoperability goals. HDABs should approach the CIP as a legally mandated public accountability infrastructure, not merely a compliance website.

The organisation of information in the CIP should consider its relation to other information sources. As discussed in chapter [3](#), the information required under Article 58 could be presented alongside the information and documents published under Article 57(1). The CIP may, for example, be organised to present dedicated sections or links for each data access application and corresponding data permit as well as for each approved health data request. These may allow users to navigate directly to the information required under Article 58(1), such as the legal basis, technical and organisational measures, or information on the rights of natural persons.

Beyond legal compliance, adopting robust governance and technical architecture is recommended to ensure long-term sustainability, interoperability across Member States, and public trust. Therefore, the CIP must ensure:

- Transparency of governance
- Transparency of access decisions
- Transparency of results
- Transparency of datasets
- Transparency of rights
- Equal access to information

A possible structure into subsections, which does not constitute a recommendation but is provided as an example, could include the following:

”Your rights”

For an *Opt-Out and Rights Information* section, the HDAB should report a clear explanation of opt-out mechanism, how to exercise it and how to reverse it, the public interest override conditions, complaint/contact mechanisms, and GDPR rights explanation.

“Who is using health data”

Introducing the citizen to the *Public Permit Transparency Register* and to its search functionality, HDABs must also preserve confidentiality of intellectual property rights, trade secrets, and other protected information in the execution of their tasks. Hence the Public Permit Transparency Register should publish a public version of each permit and refusal decision rather than the full unredacted administrative act. Each public entry should contain at least the required metadata.

“How your data is protected”

An educational section explaining the secure processing environment(s), prohibition of re-identification, pseudonymisation and anonymisation, audit mechanisms, and protection of intellectual property and trade secrets

“Project results”

A section linking to the periodic activity report from the HDAB and the sections of the register with the individual project results and its search functionality. Optional dashboards may be added, summarising data use trends. HDUs must make public the results or output of secondary use and results must contain only anonymous data. HDUs should assist the HDAB in making that information public. A best practice would be to establish a mandatory submission workflow for HDUs through the HDAB portal, so that, for each completed project, HDUs would report anonymous outputs, links to scientific publications (if applicable), and lay summaries in plain language.

If the option is chosen to allow the HDUs to publish their activity results or resources other than those managed by the HDAB, with the HDAB therefore providing links on its portal to these external resources, their long-term availability would need to be ensured. HDABs could implement an internal review mechanism verifying anonymisation adequacy, consistency with authorised purpose, and absence of re-identification risks.

“Dataset catalogue”

The HDAB makes public, through electronic means, a national health dataset catalogue including details about the source and nature of electronic health data and the conditions for making such data available. The catalogue must be publicly available, searchable, and accessible to natural persons.

Without prejudice to catalogue implementation, which is out of scope of this guideline, a best practice recommendation would be to allow for distinct front-end interfaces for different user groups (such as a Citizen Transparency Interface and a Professional Applicant Interface). To guarantee consistency these should then preferably be connected to a unified backend.

“Complaints and contact”

could report the HDAB contact details, the data protection officer contact, a link to the HDAB website, and the contact/complaint procedure explanation.

Visual explainers

Step-by-step guides, tutorials, and basic concepts can be presented with flow diagrams and infographics. Tutorials might include, for example, how to search the *Public Permit Transparency Register*, how to read a dataset description, how to exercise opt-out and how to file complaints. All tutorials should be accessible, captioned, transcribed, and screen-reader compatible.

Further considerations

With respect to information layers and/or customisability, information should be straightforward and easily understandable for individuals. The information in data permits will not be of the same interest to data subjects in all levels of detail. HDABs may therefore wish to consider options enabling data subjects to focus on the most relevant information, for example by structuring content in layers around projects grouped by specific diseases, or by making information customisable within the CIP.

For situations when a data subject needs to identify in contact with the HDAB (e.g. when exercising an individual right related to their health data) the CIP itself will usually not handle this identification procedure. It should nevertheless provide or forward to appropriate channels through which data subjects can contact the HDAB. Traditional tools such as email or telephone may not always be sufficient or appropriate.

Regarding communication methods, assisted access points, such as hospitals and public service counters, can be considered to support individuals requiring help. Printable versions or offline informational materials should also be made available to ensure access for those with limited digital connectivity or digital skills. HDABs might further consider issuing regular newsletters providing updates on ongoing activities and on the results of the secondary use of health data, to which citizens could subscribe. Such general communication may strengthen citizens’ engagement in public health and health research matters. In addition, user feedback mechanisms should be established to gather input on the clarity, usefulness, and accessibility of the information, thereby enabling continuous improvement based on citizens’ needs and experiences. Finally, the information source of the CIP should be clearly indicated. HDABs should ensure a transparent editorial model, including the identification of a named and responsible editor entity, as well as the indication of the date of “last reviewed/updated”, accompanied by regular periodic review.

7 When should the information be provided?

The HDAB must ensure that its CIP is operational at the time of the issuance of the first data permit or the first data request approval.

All information has to be published as soon as it is available (for further information, please refer to chapter 7.1). Some elements, such as initial decisions, must be published without undue delay after the decision has been made; others, such as amendments, are published when changes occur; while project results are published at the end.

7.1 Initial publication in the Citizen Information Point

First, there are publication obligations applicable to decisions of approval or refusal on data permits and data requests, within defined timeframes. Health data access applications and health data requests must be published without undue delay after initial reception (Article 57(1)(j)(ii)). Data permits issued or health data requests approved as well as refusal decisions, including their justification, must be published within 30 working days of the issuance, approval or refusal (article 57(1)(j)(iii)).

Since the information referred to in Article 58(1) reflects the conditions under which access to data is granted and is defined in the decision to issue a data permit or approve a data request, the publication of this information should occur simultaneously with the publication of the granting decision. This approach aligns with the objective of transparency towards natural persons, ensuring that the information made publicly available accurately and immediately reflects the conditions under which data applicants may access and use electronic health data. This approach also aligns with Recital 66 which provides that the “*transparency obligations complement the obligations laid down in Article 14 of Regulation (EU) 2016/679*”.

Further information on the timelines for health data access applications and health data requests can be found in document D6.3, Guideline for Health Data Access Bodies on the procedures and formats for data access.

Second, the HDAB must publish the results of the projects for which the electronic health data were used on its CIP as soon as these results are received from the health data user, to ensure transparency. Health data users have up to 18 months from the completion of the processing of the electronic health data in the secure processing environment or from having received the response to the health data request to provide these results to the HDAB, unless they are authorised to extend this deadline for justified reasons, in accordance with Article 61(4).

In addition, if a member state allows the exercise of the right to opt out under Article 71 through the HDABs, information on the opt-out procedure should be included in the CIP from the outset, and the HDAB shall ensure that it is easily accessible to natural persons.

7.2 Amendments of information in the Citizen Information Point

In the case of amendments to health data access applications or health data requests, information required under Article 58(1) should be published following the same model as the initial publication,

at the same time as the publication of the amended data permit or health data request approval and no later than 30 working days after the amendment decision.

Further information on the timelines for health data access applications and health data requests can be found in document D6.3, Guideline for Health Data Access Bodies on the procedures and formats for data access.

Once operational, the CIP must be designed to allow updates each time a new authorisation is issued or when the conditions for access and use of the data are amended in a data permit or data request approval, insofar as they affect the information referred to in Article 58. The HDAB should allow the identification of successive versions, for example by publishing updates as entries linked to the initial decision, to facilitate tracking of the changes made in conditions associated with access to electronic health data.

The time frames for publication and updates of information under Article 58 EHDS by HDABs is summarized in Table 1.

Table 1: Time frames for publication and updating of Information under Article 58 EHDS by HDABs

Publication time frame	Information concerned
Included in the CIP from its establishment.	Public information on opt-out procedures, where applicable. See Chapter 7.1 for more information.
Without undue delay after reception.	Health data access applications and health data requests. Results of projects using electronic health data. See Chapter 7.1 for more information.
At the same time as the data permit or health data request approval, and no later than 30 working days after issuance of the decision.	Legal basis for granting access, technical and organisational safeguards, data subjects’ rights and arrangements to exercise them, identity and contact details of the HDAB, and granted access details such as datasets, users, and purposes. See Chapter 7.1 for more information.
At the same time as the amended data permit or health data request approval, and no later than 30 working days after the amendment decision.	Updated information reflecting any amendments to the permit or health data request approval. See Chapter 7.2 for more information.

Annexes

Annex index

Annex number	Annex title
1	Methodology
2	User journey
3	Glossary
4	Previous workshops concerning citizens and information points under EHDS
5	Landscape analysis of health information portals

Annex 1 – Methodology

Writing and consolidation of guideline

This guideline was developed through a structured, collaborative process. The work followed a phased approach to consistency and alignment with the applicable regulatory framework.

A framing session was conducted together with experts from the European Commission to clarify the scope and legislative intent of the respective sections of the EHDS regulation as well as additional relevant frameworks.

On the basis of the framing session contributors jointly agreed to a detailed outline, including chapter structure and relevant regulatory references. Responsibility for the first drafting of sections was allocated to major contributors.

The writing was carried out in offline work by designated authors and supported by desktop research and analysis of applicable EU legal acts. During biweekly meetings contributors discussed open questions and ensured consistency with the overarching structure, traceability of all statements to legal sources and a coherent interpretation of the regulatory requirements.

After assembling a complete draft, the document will be circulated among contributors for comments. It will also be sent to representatives from DG SANTE for review and to provide regulatory guidance and ensure alignment with the EHDS framework. Feedback will be integrated and the guideline will undergo an additional review during the public consultation phase.

Landscape analysis of existing health information portals

A landscape analysis aimed to complement the guideline's quite formal, even legal perspective with a view on the landscape of existing portals of similar kinds and purposes, which provide citizen-facing information such as on health-related topics and services available in the respective country.

To gain a broad understanding, this analysis does not limit itself to EU countries. With limited resources it did not aim for a complete and methodologically sound approach but summarises observations that were achievable in the project setting thus providing a good understanding and an overview to support writing of the guideline. It sheds some light on questions such as: How does the EHDS fit into this pre-existing landscape of portals? How can it align with national efforts towards transparency? Which of the components under EHDS are already covered in some way, and how? Can learnings be derived or notable practices be identified? How do they communicate with their target audiences (e.g. the general public) and through which options?

Learnings from the landscape analysis are integrated into the guideline text. The complete summary can be found in [Annex 5 - Landscape analysis of health information portals](#).

Public consultation

During May and June of 2026, the draft guideline will be open to public consultation. All comments received will be considered, analysed and integrated into the document for any possible improvement related to coverage of scope, relevance, clarity and utility of the final guideline.

Citizens’ and patients’ input

To complement the views of experts during project work and of the general public and the wider field of experts in the public consultation with the perspective and needs of the “end users” - the citizens - additional input of citizens and patients’ representatives will be gathered through workshops. Group A will learn from citizens with no required prior knowledge about EHDS aiming at diversity of perspectives rather than a statistically sound approach. Group B will recruit patients’ representatives and citizens’ representatives across Member States with preferably some more (basic) knowledge of the EHDS.

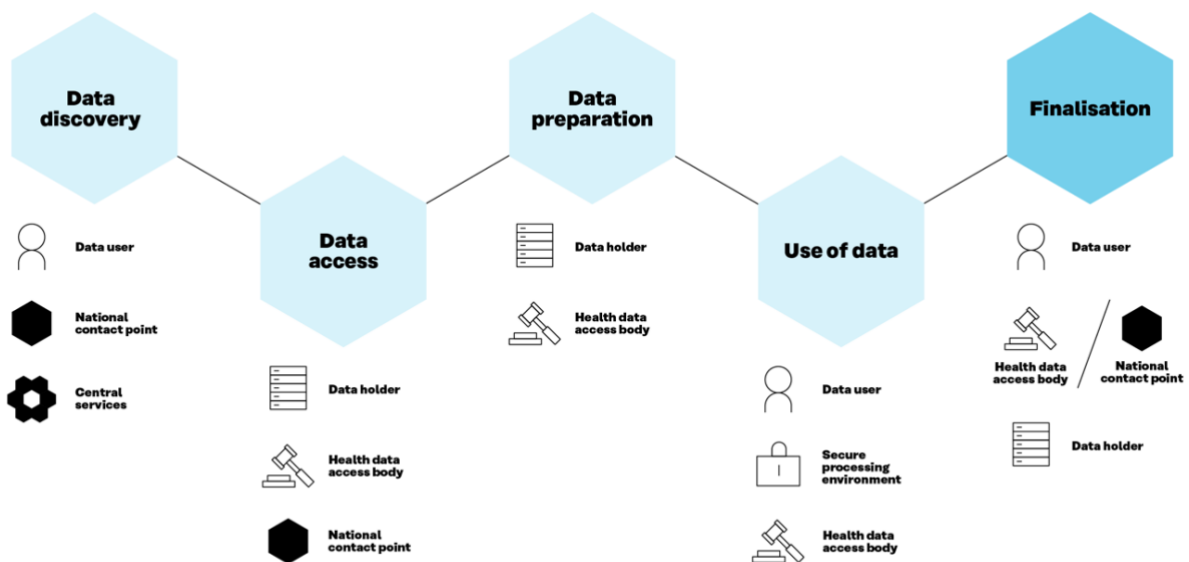
Learnings from the citizens’ and patients’ input are integrated into the guideline text, and its results are summarised in Annex 2 as part of the public consultation.

Annex 2 - User journey

This annex describes the health data access processes from the health data user perspective. This description is consistently used in the TEHDAS2 deliverables, therefore it also maintains the related terminology: Users here are not visitors to the CIP, but users of health data within the EHDS, and their user journey is described.

When a data user⁷ applies for electronic health data for secondary use purposes, such as research and innovation activities, education, and policy-making, within the European Health Data Space (EHDS), the user journey consists of several stages (see Figure 1). Access for certain purposes (public or occupational health, policy-making and regulatory activities, and statistics) is reserved for public sector bodies and Union institutions (see Chapter IV, Art. 53(1) and 53(2)).

Figure 1: EHDS user journey consists of five main phases: data discovery, data access, data preparation, use of data and finalisation.



Data discovery

Before being able to use the data, the user needs to investigate whether the data needed is available, and whether it is available in the necessary format for the secondary use purpose. This phase is called data discovery. Datasets available in the EU can be found in a metadata catalogue at <https://qa.data.health.europa.eu/>. Once the data discovery is completed, the user can begin the process of applying for the data.

⁷ Data user = a person using electronic health data for a secondary use purpose

Data access

In the data access phase, the user fills in and submits a dedicated and standardised data access application form or a data request to a health data access body (HDAB)⁸. The user must complete the information required in the form, upload necessary documents, and provide justifications as needed.

Data access application form is used when the user seeks to use personal level data. Data request is for cases when the user wants to apply for anonymised statistical data.

Data preparation

During this phase, the data holder(s)⁹ deliver(s) the necessary data to the HDAB, which starts to prepare the data for secondary use. Techniques for pseudonymisation, anonymisation, generalisation, suppression, and randomisation of personal data are employed. The data minimisation principle (as per the GDPR) must be respected to ensure privacy.

Use of data

In this phase, the user performs analyses based on the received data for the purpose defined in the application phase. Analysing personal level data must be performed in a secure processing environment¹⁰. The duration of this phase is specified in the Regulation (Art 68(12)).

Finalisation

This last phase of the user journey concerns data user’s duties regarding analysis results derived from secondary use of data. Data user must publish the results of secondary use of health data within 18 months of the completion of the data processing in a secure processing environment or of receiving the requested health data. The results should be provided in an anonymous format. The data user must inform the health data access body of the results. In addition, the data user must mention in the output that the results have been obtained by using data in the framework of the EHDS.

⁸ Health data access body (HDAB) = the authority responsible for assessing the information provided by the data user who applies for electronic health data for a secondary use purpose

⁹ Data holder = Any natural or legal person, public authority or other body in the healthcare or the care sectors that has the right or obligation to provide electronic health data for secondary use purposes or the ability to make such data available (see more EHDS Regulation Art. 2 (1t)).

¹⁰ Secure processing environment = an environment with strong technical and security safeguards in which the data user can process personal level electronic health data

Annex 3 - Glossary

Term	Definition
Anonymisation	The process by which personal data is altered in such a way that a data subject can no longer be identified directly or indirectly. (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, Recital 52; EHDS regulation, Recital 92)
Citizen Information Point (CIP)	A public information system that helps HDABs meet their legal obligations laid down in Article 58 of the EHDS regulation. It informs natural persons about the conditions under which electronic health data are made available for secondary use.
Data access	A phase in the EHDS user journey during which the user fills in and submits a dedicated and standardised data access application form or a data request to a health data access body (HDAB). The user must complete the information required in the form, upload necessary documents, and provide justifications as needed.
Data minimisation	<p>A principle mandating to only collect, store and process personal data in a manner that is adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed. (GDPR Article 5(1)(c))</p> <p>Access is only provided to electronic health data that is "adequate, relevant and limited to what is necessary in relation to the purpose of processing indicated in the health data access application by the health data user and in line with the data permit issues pursuant to Article 68." (EHDS regulation, Article 66(1))</p> <p>Data minimisation applies to all stages of the data lifecycle.</p>
Data permit	An administrative decision issued to a health data user by a health data access body to process certain electronic health data specified in the data permit for specific secondary use purposes based on conditions laid down in Chapter IV of EHDS regulation. (EHDS regulation, Article 2(2) point (v))
Data protection	<p>Processing data respecting the principles laid down in GDPR Article 5(1).</p> <p>The “implementation of appropriate administrative, technical or physical means to guard against unauthorized intentional or accidental disclosure,</p>

	modification, or destruction of data (ISO/IEC 20944-1:2013(en), 3.6.5.1).
Dataset catalogue	A collection of dataset descriptions, arranged in a systematic manner and including a user-oriented public part, in which information concerning individual dataset parameters is accessible by electronic means through an online portal. (EHDS Article 2(2) point (y))
Electronic health data	Personal or non-personal electronic health data (EHDS Article 2(2) point (c)).
Health data access application	An application form used to seek access for personal-level electronic health data for secondary use in an anonymised or a pseudonymised format. (EHDS Article 67)
Health data access body (HDAB)	Member state-designated authority that facilitates the secondary use of electronic health data. HDABs assess the information provided by the health data applicant and decide on health data requests and access applications, authorise and issue data permits, obtain data from data holders and make data available in secure processing environments. HDABs systematically track the data request and data access applications received and the data permits issued. (EHDS Article 55 and Recital 52)
Health data holder	Any person, organisation or public body involved in healthcare, care services, health-related products, wellness apps or health(care) research, that has the right to process data for health care provision or for public health purposes, reimbursement, research, policy making, official statistics or patient safety. This includes, for example, hospitals, insurers, research institutes and EU institutions. For a more detailed definition: EHDS regulation, Article 2(2) point (t))
Health data request	A request to access data in an anonymised statistical format for the purposes referred to in EHDS Article 53. (EHDS regulation, Article 69)
Health data user	A natural or legal person, including Union institutions, bodies, offices or agencies, which has been granted lawful access to electronic health data for secondary use pursuant to a data permit, a health data request approval or an access approval by an authorised participant in HealthData@EU. (EHDS regulation, Article 2(2) point (u))
Interoperability	Ability of organisations, as well as of software applications or devices from the same manufacturer or different manufacturers, to interact through the processes they support, involving the exchange of information and knowledge, without changing the

	content of the data, between those organisations, software applications or devices. (EHDS regulation, Article 2(2) point (f))
Legal basis of data processing	The criteria defined in EHDS regulation Article 68 for health data access bodies to assess whether an applicant can be given a permit to process electronic health data. The conditions under which personal data processing is considered lawful are laid down in GDPR, Article 6. Purposes for which the electronic health data can be processed for secondary use are laid down in EHDS Regulation, Article 53.
Personal electronic health data	Data concerning health and genetic data, relating to an identified or identifiable natural person, processed in an electronic form. (EHDS regulation, Article 2(2a))
Pseudonymisation	The processing of personal data in such a way that the data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure non-attribution to an identified or identifiable person. (GDPR, Article 4(5))
Public value (of data use)	For analytical or policy discussion purposes, public value could be understood as a weighted composite of risks and benefits of the data use taking into account the sustainability of benefits, addressing future societal needs, distributing benefits fairly, evaluating potential harm, ensuring stable safeguards through risk assessment, and correcting any harms that may occur.
Re-identification	The process of associating data in a de-identified <i>dataset</i> with the original data principal (i.e., data subject) (ISO/IEC 20889:2018(en), 3.31).
Re-identification risk	The risk of a successful re-identification attack (ISO/IEC 20889:2018(en), 3.33), which describes an action performed on de-identified data by an attacker with the purpose of <i>re-identification</i> (ISO/IEC 20889:2018(en), 3.32).
Secondary use	Processing of electronic health data for the purposes set out in Chapter IV of EHDS regulation, other than the initial purposes for which they were collected or produced. (EHDS regulation, Article 2(2) point (e))
Secure processing environment (SPE)	An environment in which access to electronic health data can be provided in following a data permit. A secure processing environment is subject to technical and organisational measures and security and

	<p>interoperability requirements. Specifically allowing access to only those persons listed in the permit, as well as user authentication, authorisation, restricted data handling, logging and the compliance monitoring of respective security measures. (EHDS regulation, Article 73)</p>
<p>Sensitive data</p>	<p>Data with potentially harmful effects in the event of disclosure (i.e., providing access to data to a third party) or misuse (ISO 5127:2017(en), 3.1.10.16)).</p>

Annex 4 - Previous workshops concerning citizens and information points under EHDS

1. Results from EHDS2 Workshop: Information Points for Citizens under the EHDS

Recommendations

To successfully establish Information Points for Citizens under the EHDS, we strongly recommend considering the following aspects, emphasizing that transparency is key and that there should be no secrets, except for the data itself.

Why communicate

- *“There are no secrets unless the data itself”.*
- Miscommunication and conspiracy theories will in any event impact public opinion on health data sharing, so be prepared.

What to communicate

- Why before What: always start with the impact of data sharing on public health and then explain how it is done; otherwise, you lose your audience early.
- Clear and honest information: Clearly communicate what citizens can expect from data-sharing practices, clarify the sources of health data.
- Active Involvement: Offer options for citizens to express their information preferences and get active through solid technology (integrate feedback and opt-out functionalities).
- Trust Building: Demonstrate compliance of the data sharing with legal and ethical requirements and restrictions on prohibited uses of data; explain who controls access to data, who has what access rights (i.e., roles and responsibilities).
- Openness: Integrate biobanks and other data repositories into the EHDS framework.

When to communicate

- Start your communication very early, i.e. before others do it in a way you will not like.
- Risk Management: Prepare comprehensive plans for crisis situations and miscommunication, they will occur.

How to communicate

- Positivity: Emphasize honestly the benefits and positive impacts of data sharing.
- Know Your Audience: Understand the diverse needs and perspectives of diverse groups (i.e., age, gender, disease group).
- Co-Design: Involve citizens in the design process of the national information point to manage expectations and improve acceptance.
- Layered Information: Provide information in layers to cater to diverse levels of understanding (i.e., citizens with different expertise and interest, researchers, data holders).
- Use different communication channels: Medical doctors are usually the first in line in communication with patients, involve them in your communication.
- Harmonised labelling and branding: Implement clear and consistent labelling and branding practices across Europe (minimal criteria).

Do not forget

- Resource allocation: Allocate sufficient funding and expertise for effective information sharing, including communication plans and their execution.
- Experts wanted! Do not underestimate expertise and effort needed for good communication.

2. TEHDAS1 WP8 Citizens

Work Package 8 of TEHDAS1 aimed to gain a deeper understanding of citizens’ attitudes toward sharing their health data while also identifying effective ways to inform the public about how their data are used and to raise awareness of the benefits of secondary health data use.¹¹

In the course of this work, a “*Qualitative study to assess citizens’ perception of sharing health data for secondary use and recommendations on how to engage citizens in the EHDS*”¹² (Deliverable 8.1) was undertaken. The report presents an analysis of nearly 6,000 contributions from an online consultation (carried out Dec 2021–May 2022) in France, Belgium, and the UK. The consultation was conducted prior to and independent of the European Commission’s 2022 EHDS proposal and captured citizen’s views on the future secondary use of health data. Following is a short summary on the main points regarding how citizens want to, should, and can be informed about secondary use.

Citizens consistently emphasise the need for clear, accessible information about the secondary use of their health data. While many support data sharing for the common good, particularly for research and improved care, this support is limited by low awareness of how secondary use works, why it matters, and how it differs from primary use. Citizens highlighted the importance of plain-language education, concrete examples, and visual tools such as infographics or short videos. They also called for clarification of key concepts (e.g., privacy, ownership, public interest, secondary use) to better understand legal information and build trust. Trusted intermediaries such as health professionals, patient organisations, and public institutions play a crucial role but need better training and resources. Overall, accessible and transparent information enables citizens to understand, participate in, and trust the system of secondary data use.

Beyond general awareness, citizens want the ability to access information about when and how their own data are used, while choosing how much information they receive. Preferences vary widely - from detailed personalised updates to information only on request - highlighting the need for flexible, user-centred communication options such as online portals showing ongoing projects and data uses. Stakeholders agreed that a minimum level of information must always be provided so citizens can understand and exercise their rights, while additional communication should reflect individual preferences and avoid information overload. Across citizen and stakeholder perspectives, transparency, choice, and accessible information are key conditions for trust and engagement in the secondary use of health data.

Citizens and stakeholders also stressed the importance of explaining the purposes of secondary use, who can access data, what safeguards are in place, and what societal benefits data use results in. Transparency around commercial actors and how they contribute to public benefit was viewed as especially important. At the same time, stakeholders warned that digital-only communication risks excluding groups with lower digital literacy. Together, citizens and experts called for a flexible communication framework that accommodates diverse needs, provides different levels of information, and supports meaningful involvement in the secondary use ecosystem.

¹¹ <https://tehdas.eu/tehdas1/packages/package-8-citizens/>

¹² <https://tehdas.eu/tehdas1/results/tehdas-consultation-citizens-support-the-secondary-use-of-health-data-when-it-matches-their-ethical-values/>

Annex 5 - Landscape analysis of health information portals

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1. Analysis approach

According to the THEDAS2 Grant Agreement task 8.2 performed a landscape analysis of existing health information portals. Contributing partners are GÖG, NeHA, AUH, CDEU, RIVM, MZCR.

The guideline *M8.3 Draft guideline for Health Data Access Bodies on informing natural persons about the use of health data – “Citizen Information Point”* currently being written in this task will analyse the HDABs’ responsibilities in providing such a ‘Citizen Information Point’ in the light of the EHDS regulation. The aim of this landscape analysis is to complement the guideline’s quite formal, even legal perspective with a view on the landscape of existing portals of similar kinds and purposes, which provide citizen-facing information such as on health-related topics and services available in the respective country. If and how thoroughly existing portals address also secondary use is explored with this analytic approach. To gain a broad understanding, this analysis does not limit itself to EU countries but includes a scope of European countries that could be covered in the available time.

Thereby, the analysis can shed some light on questions such as: How does the EHDS fit into this pre-existing landscape of portals? How can it align with national efforts towards transparency? Which of the components under EHDS are already covered in some way, and how? Can learnings be derived or notable practices be identified? How do they communicate with their target audiences (e.g. the general public) and through which options?

The main audience of the guideline is HDABs being responsible for CIPs, while the audiences of the existing portals covered in this landscape analysis are citizens, patients, practitioners, or other groups. Therefore, this exercise should support the uptake of the perspectives of these audiences and provide HDABs with a resource to learn from and align with existing solutions and build their CIPs in context of (and possibly as an integral part of) a wider landscape instead of isolated partial solutions.

DISCLAIMER: This work did not aim for a complete and methodologically sound approach which would have been a task of its own and required many more resources. Instead, we tried to maximise our learnings in very limited time and prepare a summary that provides the authors of the guideline with a good understanding and an overview to support them in the task’s main responsibility of writing the guideline. Therefore, aspects like the scope of examined portals or the subjective impressions of researching partners have not been validated systematically. Instead, we drew on commonly known examples, and the expertise and good judgement of the diverse group of contributors.

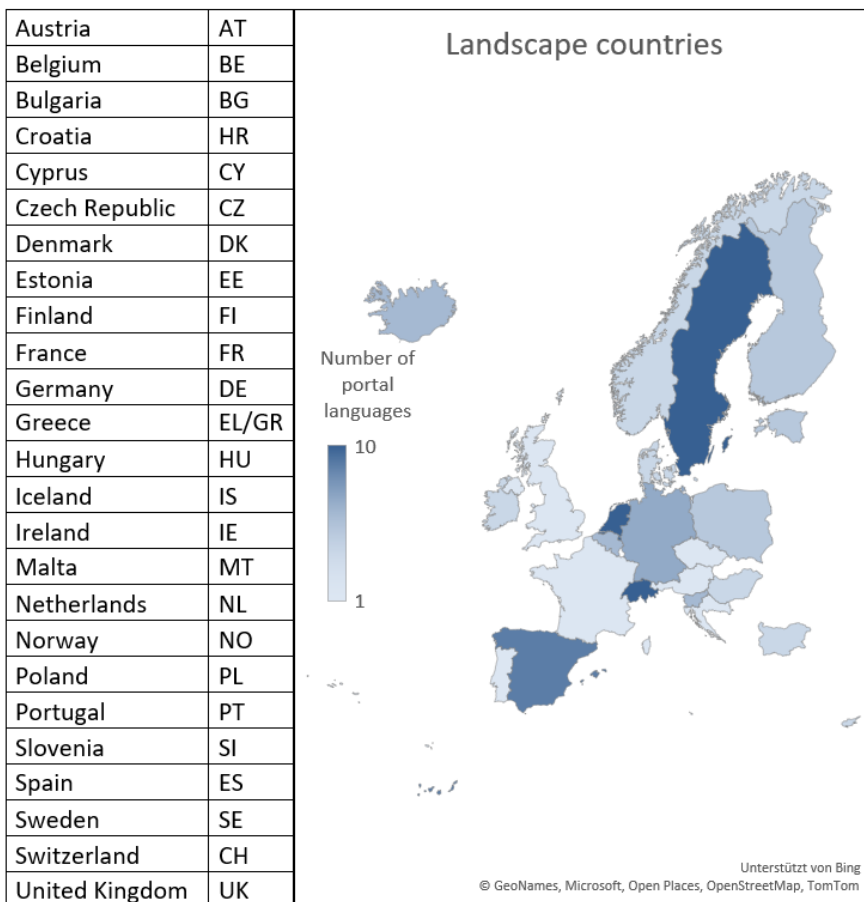
The following procedures, intermediate results, and arising questions or uncertainties were discussed and aligned in more detail in a series of collaborative bi-weekly meetings. First, a list of portals to be analysed was compiled by desk research looking for portals dealing with health (information) or use of health data. Then a list of aspects to gain an understanding of each portal (e.g. target audience(s), user friendliness) was discussed, and the details of which information to collect and how were defined, resulting in a matrix like table for data collection, which this analysis

summarises. Each partner was responsible for researching a few portals and filling out the table. Then this present summary document was structured according to the guideline’s main body of chapters, and the collected aspects were assigned accordingly. Two partner organisations were mainly responsible for each chapter, summarising in it the related aspects to outline commonalities, differences, best practices, examples and other notable observations in all the portals that have been researched. All contributors provided feedback to all chapters enriching summaries with their observation of these aspects.

2. What is an information point?

This landscape analysis is based on a desk research approach, which covers a total of 25 countries and their respective health information/data portals. In a few cases, this analysis includes multiple portals of the same country (specifically Finland with two and the Netherlands with three), which increases the number to 28 included portals. While this adds to the plurality of information and insights, the following narrative analysis is done under consideration of this fact to not over- or under-represent any of the included countries. Figure 1 below depicts the countries covered, including the number of languages in which the portals are translated (by its providers, not internet browsers).

Figure 1 Landscape countries



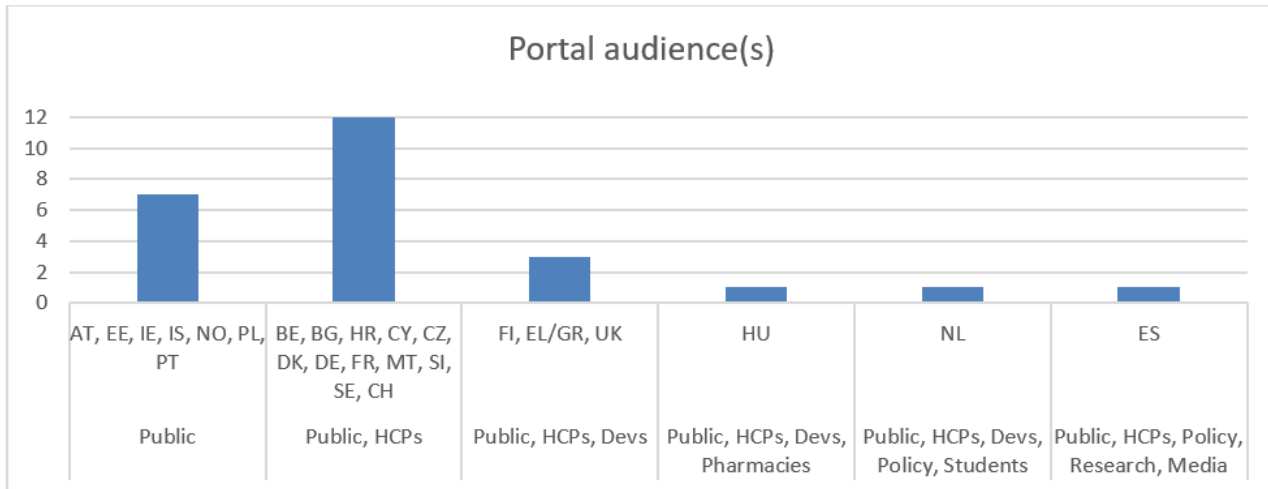
As the colour coding indicates, most of the countries’ portals, in total 22 out of the 28 portals, are maintained as a multi-lingual health information/data portal. Whereas in the case of seven bilingual portals the second language is always English, the other multilingual portals offer oftentimes up to five languages, and four countries (CH, ES, NL, SE) even eight or more language versions of their portals, including minority or high-need languages. A similar distribution, yet seemingly uncorrelated, concerns the variety in target audiences.

All the portals do have the general public as their main target audience. However, most of them target additional audiences, mainly the broad

sector of health care professionals (HCPs), which in total 19 out of the 25 countries address too. While about half of the cohort exclusively targets the general public and HCPs, some portals address in addition also software developers (in five countries) as well as stakeholders from the realms of

policy, research, media and education/students. Figure 2 provides an overview of the portals’ target audience(s).

Figure 2 Portal target audiences



Portals provide their audience(s) with a multitude of health topics mainly in the primary use domain. The topics cover a range of health-related information (e.g. on diseases, treatments, wellness, patient guides, patient rights) and/or information about health services available both digitally (e.g. medication, prescription, lab results, imaging, vaccinations, patient decree, organ and data donation) and in-person (e.g. appointments, healthcare map). While about half of the portals do address also the domain of secondary use of health data, only a few address it through details, such as providing the option of data donation and information on how data is handled (FI, FR, SI, UK), by mentioning open and past surveys, or reporting on outcomes in studies and health statistics (ES, FR, NL).

In most cases, the health information/data portal’s authority is the country’s Ministry of Health (about two thirds of the 25), which in some instances is also responsible for other fields (e.g. Social Affairs/Care, Consumer Protection, Environment, Food Chain Safety). In other cases, the portal’s ownership and responsibility is shared by the Ministry of Health with other actors, such as from the regions and municipalities (DK), Social Insurance (FI), IT development (NO) or statistics (CZ). Alternatively, the portal’s authority is held by other single actors, such as federal IT services (EE, EL/GR), Health insurance (FR), eHealth institutions (CH), college of GPs (NL) as well as IT companies that provide and develop the services (NL, SE).

Notable examples that cover multiple languages, audiences, and address secondary use out of practice are the portals of ES and NL.

3. What information shall be provided?

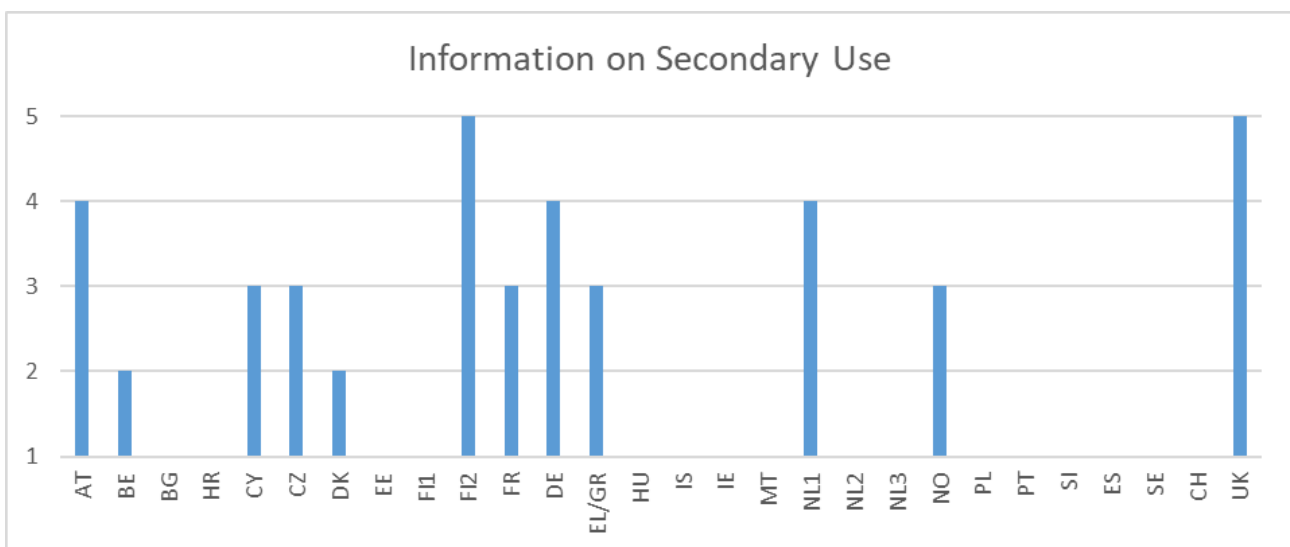
Across the reviewed portals in the selected countries, information on access to health data in general is relatively widespread, but uneven in terms of depth, clarity, and scope. In most cases, citizens are informed that access to health data exists and that they have rights to their personal data based on legal acts, particularly GDPR. However, such information predominantly relates to the primary use of health data, particularly access related to electronic health records and sharing of data.

Explicit references to the legal basis for data access, such as national legislation or the EHDS, are typically limited or indirect and are often provided via links to full legal frameworks rather than being

clearly explained in citizen-oriented terms. Only a minority of countries provide direct links to, or structured explanations of, the relevant legal foundations, and even in these instances the emphasis remains mainly on primary use.

Currently, information about secondary use is far less widespread and generally less developed than information about primary use. In rare cases, the reuse of health data for research is mentioned but not in a dedicated overview. Such information is typically provided with the aim of explaining that the collected data is not misused. Using the provided scoring (1-5), where 1 indicates very limited information and 5 indicates detailed information, the landscape looks as follows.

Figure 3 Information on secondary use



Our assessment shows variance with a few portals scoring quite high and the majority rather low:

- Detailed information (score 4-5): Austria, Finland (portal 2), Germany, the Netherlands (portal 1), and the UK provide relatively detailed information on secondary use.
- Moderate information (score 2-3): Belgium, Cyprus, Czech Republic, Denmark, France, Greece, the Netherlands (portal 3) and Norway provide some information on secondary use, but it is limited in scope.
- Limited information (score 1 or “no”): Bulgaria, Croatia, Estonia, Finland (portal 1), Hungary, Ireland, Island, Malta, the Netherlands (portal 2 and 3), Poland, Portugal, Slovenia, Spain, Sweden, and Switzerland provide little to no information on secondary use.

Some countries (e.g. DK, FI) have additional health data portals that are less citizen-oriented but provide information about secondary use of health data. The UK portal (NHS¹³), for instance, offers a wide range of information about secondary use of health data, which is structured either as a general overview of the purpose of this use or as information for data users about the available options for them. Most of the information is about the Secondary Uses Service (SUS) and the NHS Research Secure Data Environment (SDE) Network, but neither of the sections targets individuals, nor are they designed for patients’ viewpoints (with the exception of opt-out, see below).

Regarding information on opt-in/-out/consent management, most health data portals provide information on individual rights and consent options, often in lay language. When specified though,

¹³ <https://digital.nhs.uk>

this typically applies to primary use of data only. Five of the reviewed portals present information related to opt-in/opt-out on data sharing for primary purposes (HR, DK, FR, IS, MT), while five others (FI, NO, SE, UK, NL) add or deal exclusively with such options for data subjects on the secondary use of health data.

Although the UK’s NHS portal’s opt-out regulation does not fall under the EHDS regulation, it is an example for providing comprehensive information for citizens regarding opt-out service in the so-called National Data Opt-Out (NDOO), which allows individuals to choose, in specified circumstances, if data from their health records is shared for healthcare research and planning. Furthermore, there is information about the service, its purpose, development over time and who it is for, as well as about benefits of secondary use of health data, national (health data) usage policy, examples, when opt-out can be overridden and other details including contacts that citizens may need, such as when using one of the four pathways (via app, phone, email, post) to opt-out.

Summary of the mandatory information availability

Across the reviewed countries, most health data portals do not provide information about specific instances of secondary use or their results. Very few portals report on research projects, or the data permits that allow them to be carried out, and very few provide aggregated information on secondary use. If there is information that was created on the basis of secondary use of health data, it is produced by the owner of the portal and typically presents statistical information about certain aspects of healthcare (UK, CZ, FR) or even offers open data (FR). A small number of portals do report on specific projects (BG, CZ, FI via an external site, UK) and in aggregated form (ES, FI via an external site, UK), but these remain exceptions.

Overall, transparency regarding secondary use of health data is rather limited, both for individual projects and aggregated reporting, making it difficult for citizens to see how their data is used.

Across the reviewed countries, all health data portals provide some form of user support, though the available channels vary. Most portals offer helpdesk services via email and phone. In addition to these, some portals provide chat or chatbot support (DK, FI, NL, NO), or more specialized options such as videocall support for sign language (SE) or face-to-face counters (PT). A small number relies mainly on contact forms (e.g. BE, CZ), while one of the Netherlands portals focuses on professional collaboration rather than direct citizen support.

4. What information can be provided?

Educational resources & community features

Across the portals where this was documented, educational content is much more common than true “community” functionality. Many portals offer FAQs, articles/news items and practical guides/how-to content and a noticeable subset add glossaries/terminology help, a helpful pattern when portals touch complex topics like data access. In contrast, forums or in-portal support groups are uncommon, “community” is more often implemented as social media integration/links, occasional blogs/news feeds, or links to external self-help groups rather than moderated peer spaces.

A clear best-practice pattern is when portals combine FAQs + step-by-step guides and plain explanations (and ideally tutorials) rather than relying on FAQs alone, because it supports both first-time users and returning users looking for specific actions.

Languages & audience options

Language coverage varies widely. A substantial group of portals is single-language, many others provide two languages (often the national language plus English), and a smaller, but important, group

offers four or more languages, sometimes including minority or high-need languages. English availability is common where multilingual support exists, suggesting an implicit “minimum viable” approach for cross-border accessibility.

Information sources & review process

Where specified, portals most often cite public authorities and/or medical professionals as content owners, sometimes complemented by accredited external bodies or scientific institutions (a strong credibility signal when clearly presented). However, source attribution is frequently missing or generic, making it harder for users to judge trustworthiness at the point of use. The biggest gap is the review process (S): only a minority of portals clearly describe who reviews content and how often (e.g., regular expert review, annual cycles, or multi-year editorial review windows).

The strongest practice is to publish a transparent editorial model: named responsible entity, review cadence and ideally “last reviewed/updated” metadata and evidence basis, this tends to build trust more effectively than simply stating content is “updated regularly.”

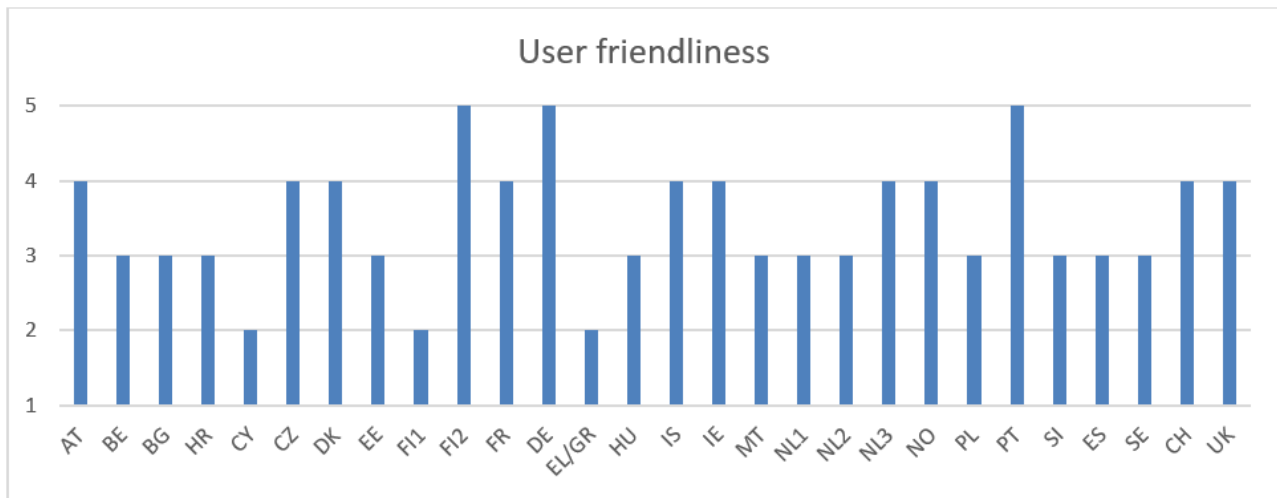
5. How should the information be provided?

Most of the reviewed portals had effective search tools available. However, a few indicated a complete lack of search functionality, relying instead on elements such as headers to navigate.

On the other hand, the desk research shows a mixed picture regarding the availability of tools such as symptom checkers, health calculators, or risk assessments related to primary use. A minority of portals provide direct access to symptom checkers, health calculators, or decision aids. Relevant examples include the Austrian [Gesundheit.gv.at](https://www.gesundheit.gv.at) containing health calculators; the Danish [sundhed.dk](https://www.sundhed.dk), albeit targeted towards health professionals; and chatbots or system checkers in some other countries (FI, NL, NO, PL, SE). However, the majority of portals indicated the absence of such tools.

Across the reviewed countries, the ease of navigation and user friendliness of health data portals were assessed on a scale from 1 (challenging) to 5 (easy), based on the authors’ experience doing desk research. The average score across all portals was 3.4, indicating moderate user-friendliness overall. While most portals received ratings of either 3 or 4, notable outliers emerged, as three portals (FI2, DE, PT) achieved the highest score (5), reflecting a particularly strong user experience. However, also only three received low scores of (2) (CY, FI1, EL/GR), and none received the lowest score (1).

Figure 4 Portal user friendliness



Regarding compliance with accessibility standards, e.g., for visually impaired users, most services report partial compliance with accessibility standards. They primarily reference relevant national or European legislation, such as the European Accessibility Act (EU 2019/882) or the Web Content Accessibility Guidelines (WCAG) criteria 2.1 or 2.2, as mandated by national law. Some findings likewise emphasised certain accessibility features, such as display options, sign language support or the use of simplified language.

On the other hand, the use of videos, infographics, and other multimedia elements varies across the analysed portals. A majority shows some level of multimedia use, most commonly videos, accompanied by graphics or infographics. In a few cases, multimedia content is enhanced with accessibility features, such as sign language and subtitles. However, several portals indicate no use of multimedia at all, while a small number show limited or indirect use (e.g. multimedia mainly on public-facing platforms or interactive maps).

The availability of dedicated mobile applications also paints a diffuse picture. While more than half of the portals offer a dedicated app, a substantial share had no such app or no clear information. In contrast, with only two exceptions, mobile-friendly websites are nearly universally available.