



EUROPEAN COMMISSION

## **PROTECTION OF YOUR PERSONAL DATA**

**Processing operation:** eHDSI ArtDecor

**Data Controller:** European Commission, DG SANTE, Unit C1

**Record reference:** DPR-EC-00063.2

### **Table of Contents**

- 1. Introduction**
- 2. Why and how do we process your personal data?**
- 3. On what legal ground(s) do we process your personal data?**
- 4. Which personal data do we collect and further process?**
- 5. How long do we keep your personal data?**
- 6. How do we protect and safeguard your personal data?**
- 7. Who has access to your personal data and to whom is it disclosed?**
- 8. What are your rights and how can you exercise them?**
- 9. Contact information**
- 10. Where to find more detailed information?**

## 1. Introduction

The European Commission is committed to protect your personal data and to respect your privacy. The Commission collects and further processes personal data pursuant to [Regulation \(EU\) 2018/1725](#) of the European Parliament and of the Council on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data.

This privacy statement explains the reason for the processing of your personal data for the ART-DÉCOR Clinical Document Architecture (CDA) Template Management Tool (ART-DÉCOR). It explains the way we collect, handle and ensure protection of all personal data provided, how that information is used and what rights you have in relation to your personal data. It also specifies the contact details of the responsible Data Controller with whom you may exercise your rights, the Data Protection Officer and the European Data Protection Supervisor.

The information in relation to the processing of personal data for the ART-DÉCOR Clinical Document Architecture (CDA) Template Management Tool (ART-DÉCOR) is presented below.

## 2. Why and how do we process your personal data?

Purpose of the processing operation: Our unit collects and further processes your personal data for the following purposes which are necessary for the administration of the ART-DÉCOR Clinical Document Architecture (CDA) Template Management Tool (ART-DÉCOR).

ART-DÉCOR is an Open-Source tool suite for various multidisciplinary stakeholders in the field of definition of standards for use in the health domain related to developing commonly agreed templates for presentation of clinical documents such as patient summary, electronic prescriptions, electronic dispensations and other. The tool supports the creation and maintenance of templates which are compliant to the Health Level Seven International (HL7) related standards. ART-DÉCOR supports the creation and maintenance of Health Level International (HL7) templates, value sets of the clinical terms, scenarios of the various clinical documents (Patient Summaries, ePrescriptions, eDispensations) and data sets aiming at creating commonly agreed formats between the Member States for further use in the eHealth Digital Service Infrastructure cross-border exchange of health information (eHDSI CBeHIS). The tool and the templates managed by ART-DÉCOR are publicly available.

However, a restricted area is available to limited and registered users. Only the privileged users can modify existing templates. Your personal data are registered only for system use and system operations and administration. They are requested, submitted, collected, stored and used only for the purposes of accessing or operating the tool.

The tool does not process any personal health data. The personal data collected are data required for granting access to the registered users.

Your personal data will not be used for any automated decision-making including profiling.

## 3. On what legal ground(s) do we process your personal data?

The Legal Basis for the ART-DÉCOR processing of personal data is the following:

- Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare;
- Commission Implementing Decision 2019/1765 providing the rules for the establishment, the management and the functioning of the network of national responsible authorities on eHealth;
- Regulation (EU) N° 283/2014 of 11 March 2014 on guidelines for trans-European telecommunications networks and repealing Decision N° 1336/97/EC;
- Regulation (EU) No 1316/2013 establishing the Connecting Europe Facility (CEF);
- Connecting Europe Facility (CEF) Work Program 2016.
- Commission recommendation 2008/594/EC on cross-border interoperability of electronic health record systems.

While requesting access to ART-DÉCOR, your personal data will be collected and processed for the purposes detailed hereafter under point 2.

Consequently, those processing operations are lawful under Article 5(1)(a) of Regulation (EU) 2018/1725 (processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the Union institution or body).

#### **4. Which personal data do we collect and further process?**

The following personal data may be processed through the ART-DÉCOR:

- Username;
- Email address;
- First and Last name;

#### **5. How long do we keep your personal data?**

Personal data recorded through the eHDSI ART-DECOR are retained for as long as the system is being used by the user. The users can request to have their data inactivated or erased at any time. If the users do not access the system for **five (5) years**, their personal data will be deleted from the system after this period expired.

#### **6. How do we protect and safeguard your personal data?**

All personal data in electronic format are stored on the servers of the European Commission or of its contractors. All processing operations are carried out pursuant to [Commission Decision \(EU, Euratom\) 2017/46](#) of 10 January 2017 on the security of communication and information systems in the European Commission.

In order to protect your personal data, the Commission has put in place a number of technical and organisational measures. Technical measures include appropriate actions to address online security, risk of data loss, alteration of data or unauthorised access, taking into consideration the risk presented by the processing and the nature of the personal data being processed. Organisational measures include restricting access to the personal data solely to authorised persons with a legitimate need to know for the purposes of this processing operation.

Selected service providers for organisational purposes (third party contractor) are contractually bound to process personal data on behalf of and in line with the instructions of the data controller, keep confidential any data they process and protect it from unauthorised access.

Specifically, for the data processing in question, the collected personal data related to eHDSI ART-DECOR are hosted and stored at the Amazon Web Services (AWS Cloud), as third party subcontractor, under an agreement with DIGIT. They are bound by a specific contractual clause for any processing operations of your personal data on behalf of the Commission, which includes the obligation to put in place appropriate technical and organisational measures to ensure the level of security required by the Commission. The user data including administrators' data are stored in the Amazon Web Services (AWS Cloud) with location in Ireland. The service provider AWS has no permission privileges of access to the user data either via the admin console of the tool or via the backup files. More information on the standard data privacy measures within the Amazon Cloud AWS can be found on their official web page: <https://aws.amazon.com/compliance/data-privacy-faq/>.

## **7. Who has access to your personal data and to whom is it disclosed?**

Access to your personal data is provided to the Commission staff responsible for carrying out this processing operation and to other authorised Commission staff according to the “need to know” principle. Such staff abide by statutory, and when required, additional confidentiality agreements.

In addition, the following categories of people have access to your personal data: Commission External Service Providers (intra-muros) under an external contract with DG SANTE, Unit R4, Information Systems. They have access to the personal data stored in the ART-DECOR, for administration and maintenance purposes.

To the extent that our unit will collaborate with other entities for the management of the ART-DECOR, the entities at hand will have access to this data so that they can exercise their tasks.

The cookies employed by the Commission on the registrant’s device for purpose of registering are covered by the cookie policy of the Commission, which is available here: [https://ec.europa.eu/info/cookies\\_en](https://ec.europa.eu/info/cookies_en).

## **8. What are your rights and how can you exercise them?**

You have specific rights as a ‘data subject’ under Chapter III (Articles 14-25) of Regulation (EU) 2018/1725, in particular the right to access, your personal data and to rectify them in case your personal data are inaccurate or incomplete. Where applicable, you have the right to erase your personal data, to restrict the processing of your personal data, to object to the processing, and the right to data portability.

You have the right to object to the processing of your personal data, which is lawfully carried out pursuant to Article 5(1)(a) of Regulation (EU) 2018/1725 on grounds relating to your particular situation.

In case you want to verify which personal data are stored on your behalf by the responsible Controller, have it modified, corrected, or deleted, you can perform this operation according to your rights and permissions as Commission External Service Provider (intra-muros).

Special attention is drawn to the consequences of a delete request, in which case any trace to be able to contact you will be lost.

In case you have questions related to the ART-DECOR, please contact the support team, operating under the responsibility of the Controller, using the following contact information: [SANTE-EHEALTH-DSI-SUPPORT@ec.europa.eu](mailto:SANTE-EHEALTH-DSI-SUPPORT@ec.europa.eu).

You can exercise your rights by contacting the data controller, or in case of conflict the Data Protection Officer. If necessary, you can also address the European Data Protection Supervisor. Their contact information is given under Heading 9 below.

Where you wish to exercise your rights in the context of one or several specific processing operations, please provide their description (i.e. their Record reference(s) as specified under Heading 10 below) in your request.

## **9. Contact information**

### **- The Data Controller**

If you would like to exercise your rights under Regulation (EU) 2018/1725, or if you have comments, questions or concerns, or if you would like to submit a complaint regarding the collection and use of your personal data, please feel free to contact the Data Controller, SANTE-CONSULT-C1@ec.europa.eu.

### **- The Data Protection Officer (DPO) of the Commission**

You may contact the Data Protection Officer ([DATA-PROTECTION-OFFICER@ec.europa.eu](mailto:DATA-PROTECTION-OFFICER@ec.europa.eu)) with regard to issues related to the processing of your personal data under Regulation (EU) 2018/1725.

### **- The European Data Protection Supervisor (EDPS)**

You have the right to have recourse (i.e. you can lodge a complaint) to the European Data Protection Supervisor ([edps@edps.europa.eu](mailto:edps@edps.europa.eu)) if you consider that your rights under Regulation (EU) 2018/1725 have been infringed as a result of the processing of your personal data by the data controller.

## **10. Where to find more detailed information?**

The Commission Data Protection Officer (DPO) publishes the register of all processing operations on personal data by the European Commission, which have been documented and notified to him. You may access the register via the following link: <http://ec.europa.eu/dpo-register>.

This specific processing operation has been included in the DPO's public register with the following Record reference: DPR-EC-00063.2.