

Deliberation 2023-002 of January 12, 2023 National Commission for Computing and Liberties Nature of the deliberation: Other authorization Legal status: In force Date of publication on Légifrance: Tuesday January 24, 2023 Deliberation n° 2023-002 of January 12, 2023 authorizing the company ELSAN SAS to implement automated processing of personal data for the purpose of setting up a health data warehouse, called "EDS ELSAN". (authorization request no. 2226980)

The National Commission for Computing and Liberties, Seizure by the company ELSAN SAS of a request for authorization concerning the automated processing of personal data for the purpose of setting up a health data warehouse called EDS ELSAN; Having regard to Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (RGPD); Having regard to law n° 78-17 of January 6, 1978 as amended relating to data processing, files and freedoms (data-processing law and freedoms), in particular its articles 44-3° and 66- III; Having regard to deliberation no. 2021-118 of October 7, 2021 adopting a reference system relating to the processing of personal data implemented for the purposes of creating a data warehouse in the field of health; On the proposal of Ms. Valérie PEUGEOT, commissioner, and after having heard the observations of Mr. Benjamin TOUZANNE, government commissioner; Formulates the following observations: On the responsibility for treatment The company ELSAN SAS is a player in private hospitalization in France comprising 137 establishments health throughout the territory. The group's establishments offer medicine, surgery and obstetrics, dialysis, emergency services, follow-up and rehabilitation care, home hospitalization, radiology, nuclear medicine and radiotherapy and take care of more than 2,200,000 patients per year. On the subcontractors Several subcontractors will be involved in the implementation of this warehouse. The processing of data by each of these subcontractors must be governed by a contract or a legal act, in accordance with Article 28 of the GDPR. On the purpose of the processing, its lawfulness and the conditions for processing data concerning health The purpose of the processing envisaged is to create a warehouse of personal data including health data, called EDS ELSAN. The purpose of the latter is to: carry out routine analyzes with the production of indicators for management purposes medico-economic, operational and strategic and for improving the quality of care; the performance of analyzes with the production of indicators with a view to assessing the feasibility of research on cohorts at the scale of the ELSAN group; the performance of studies, research, evaluations in the field of health. The purpose of the processing is determined, explicit and legitimate, in accordance with the provisions of article 5-1-b) of the RGPD. The data contained in this warehouse cannot, by analogy with the prohibited purposes of use of the National Health Data System

(SNDS), be used for the purposes of promoting the products mentioned in II of Article L. 5311-1 of the Public Health Code towards professionals of health or health establishments, nor for the purpose of excluding guarantees from insurance contracts, nor for modifying contributions or insurance premiums for an individual or a group of individuals with the same risk. The processing implemented by the data controller is necessary for the purposes of the legitimate interests that it pursues. This processing is, under this legal basis, lawful under Article 6-1-f) of the GDPR and fulfills the conditions allowing the processing of data concerning health under the provisions of Articles 9-2- j) of the GDPR and 44-3° of the amended Data Protection Act. Future uses of the data contained in this warehouse will fall within the framework of the provisions of Articles 66 and 72 and following of the Data Protection Act, which impose that each research project, study or evaluation be justified by the public interest. This processing must be subject to its own formalities. On the point of non-compliance with the relevant standard The application file mentions that the planned processing complies with the provisions of the data warehouse standard in the field of health, with the exception of the legal basis of the processing. Apart from this point, which is the subject of a specific examination in this authorization, this processing must respect the framework provided for by the repository of data in the field of health. On governance The data controller has set up a governance system for the EDS ELSAN warehouse in order to control the use that will be made of it in compliance with the declared purposes and the public interest. This system is made up of: an operational steering committee, which is responsible in particular for data management, respect for the rights of the persons concerned, proposing to the strategic committee operational guidelines to be given to the warehouse, managing requests for access to data, to ensure compliance with safety rules and to formalize an annual report on the operation of the warehouse. He is also in charge of maintaining an exhaustive list of data and justifying their need; a strategic committee, which determines the strategic orientations of the warehouse and the resources to be allocated. In particular, he is responsible for ensuring the definition and compliance with good operating practices for the warehouse and validating the authorizations given on a permanent basis for access to data; a scientific and ethics committee for research , whose mission is in particular to evaluate and approve project proposals requiring the reuse of data from the warehouse. On the data processed Personal data of healthcare professionals and patients cared for by healthcare establishments from the ELSAN group and stored in the warehouse are: patient data, from care and collected as part of care: medical observations and progress reports; personal and family, medical and surgical history; family situation, lifestyle, sex life; professional situation, schooling, training, occupational exposure; notes and opinions of health professionals; paramedical and medico-social transmissions; evaluation by the patient

of his state of health and his satisfaction; prescription and administration of products, medical and paramedical acts and health benefits medicines; establishment, service, functional care unit; programming and performance of medical and paramedical acts; drug administration; use and traceability of medical devices; management report: consultation, visit to the emergency room, hospitalization, anesthesia, surgery; report of additional examinations (imaging, biology); letters from health professionals; medical monitoring data: physiological constants; medical biology results; pathology results; imagery and video data; date, place and cause of death; INSEE data relating to deceased persons: INSEE death file and INSEE death opposition file; structured data from the information system medicalization program (PMSI): establishment; doctor responsible for the stay; prescribers; diagnoses; acts carried out; information relating to pregnancy monitoring and newborns; administration of products subject to a collection of specific information (list of products and services and common dispensing units); installation or use of medical devices subject to specific information collection (list of products and services); medical responders; paramedics billing acts; patient identification data: registration number in the national identification directory of natural persons (NIR); identifier in the warehouse; permanent patient identifier establishments; medical record identifier; use name ; birth name ; first names; date of birth ; gender ; Residence address ; telephone number; email; doctors' data: civility; name ; first name ; year of birth ; number in the shared directory of healthcare professionals (RPPS); job title and specialization; establishment, service, functional unit; connection and entry logs; data from paramedical workers billing acts: Adeli number; specialty. These data will be pseudonymized before their integration in the warehouse. In accordance with the reference system, the NIR of the patients will be on the one hand, preserved encrypted and, on the other hand, pseudonymized in an irreversible way to feed the warehouse. These data are adequate, relevant and limited to what is necessary with regard to the purposes of the processing, in accordance with the provisions of article 5-1-c) of the GDPR. warehouse twenty years from their collection and then deleted. Functional and technical traces are kept for one year. These data retention periods do not exceed the period necessary for the purposes for which they are collected and processed, in accordance with the provisions of Article 5-1-e) of the GDPR.

accessors and recipients of data will be able to access personal data: specifically authorized ELSAN personnel, subject to professional secrecy, within the strict limits of their need to know for the exercise of their missions falling within the purposes of the EDS ELSAN warehouse; external partners, public or private bodies, sponsors of study, evaluation or research projects in the field of health who have carried out the necessary formalities with the Commission. referred to above, applicants may only be recipients of reports containing aggregated and anonymized data. On information and the rights of individuals As regards

patients treated prior to the creation of the warehouse and no longer followed: Pursuant to Article 69 of the law and Article 14-5-b) of the GDPR, the obligation to provide individual information to the person concerned may be subject to exceptions, in particular in the event that the provision of such information would prove to be impossible, would require disproportionate efforts or would seriously compromise the achievement of the objectives of the processing. In such cases, the controller shall take appropriate measures to protect the rights and freedoms, as well as the legitimate interests of the data subject, including by making the information publicly available. In this case, an exception will be made to the principle of individual information of the participants supported prior to the constitution of the warehouse and no longer being monitored. Appropriate measures will be implemented, in particular by dissemination on the website of the study controller, on social networks and by press release, as well as by posting in ELSAN health establishments, information containing all the information provided for by the GDPR.

With regard to patients treated after the establishment of the warehouse: An individual information note, containing all the information provided for by the GDPR, will be given to patients and, where applicable, their legal representatives, at the time of their treatment. With regard to doctors and paramedics billing for procedures: Doctors and paramedics billing for procedures and whose data are entered into the warehouse will receive an individual information note, including all of the information provided for by the GDPR. With regard to warehouse users: Users are informed of the collection of their data when they connect and before sending the login and password. The rights of individuals are exercised with the data protection officer of the care institution or the data protection officer of ELSAN. Information relating to the constitution of the database called EDS

ELSAN cannot replace the prior individual information provided for by the provisions of the GDPR and the Data Protection Act, which must be carried out for each data processing carried out from data from the warehouse. On data transfers This decision does not constitute authorization to transfer data outside the European Union, to a country that does not offer an adequate level of protection. On data security and traceability of actions As a preliminary point, the Commission takes note that the application file mentions that the planned processing complies with all the security measures provided for in the data warehouse repository in the field of health. The processing manager has carried out and transmitted in support of the request for authorization an impact analysis relating to data protection specific to the creation of the warehouse. The supply of the warehouse with health data from health establishments will be carried out in the form of an encrypted archive, accessible for a limited time in a secure area. An automatic purge is planned as soon as the data is recovered. The data controller must ensure compliance with the requirements of the health data warehouse repository for data exchanges entering and leaving the

warehouse. The security measures, which must be operational during the implementation of the processing, will then meet the requirements of Articles 5.1, f) and 32 of the GDPR, taking into account the risks identified by the controller. It will be up to the data controller to carry out a regular reassessment of the risks for the persons concerned and an update, if necessary, of these security measures. Authorizes, in accordance with this deliberation, the company ELSAN SAS to implement , under these conditions and in accordance with its action plan, processing of personal data for the purpose of setting up a health data warehouse called EDS ELSAN for a period of ten years. The President Marie-Laure DENIS