

Deliberation 2019-082 of June 20, 2019 National Commission for Computing and Liberties Nature of the deliberation:

Authorization Legal status: In force Date of publication on Légifrance: Saturday July 11, 2020 Deliberation n° 2019-082 of June 20, 2019 authorizing the National Institute of Cancer (INCa) to implement automated processing of personal data for the purpose of setting up a health data warehouse aimed at studying the trajectories of people with cancer, entitled: "Oncology data platform (request for authorization no. 918314) The National Commission for Computing and Liberties, Seizure by the National Cancer Institute of a request for authorization relating to the automated processing of personal data for the purpose of constitution of a health data warehouse aimed at studying the trajectories of people with cancer; Having regard to Convention No. 108 of the Council of Europe for the protection of individuals with regard to the automatic processing of personal data; 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 personal data and the free movement of such data, and repealing Directive 95/46/EC; Having regard to Law No. 78-17 of 6 January 1978 as amended relating to data processing, files and freedoms, in particular its articles 44-3° and 66 and following; Considering the law n° 2016-41 of January 26, 2016 of modernization of our health system, in particular its article 193; Having regard to the decree n° 2016-1871 of December 26, 2016 relating to the processing of personal data referred to as the National Health Data System; Having regard to Decree No. 2019-536 of May 29, 2019 taken for the application of Law No. files and freedoms; Having regard to the decree of March 22, 2017 relating to the applicable to the National Health Data System; Having regard to decision DE-2011-058 of June 11, 2012 authorizing INCa to implement the processing of personal health data for the purpose of creating dashboards and study of the trajectory of cancer patients based on data from the Commission's SNIIRAM (Authorization request no. 911297); After hearing Mrs. Valérie PEUGEOT, Commissioner, in her report, and Mrs. Nacima BELKACEM, Government, in its observations, Formulates the following observations: On the data controller The National Cancer Institute (INCa), whose missions are specified in Article L. 1415-2 of the Public Health Code (CSP), is the State agency for health and scientific expertise in oncology responsible for coordinating actions to fight cancer. On the purpose of the treatment and its formality In 2012, INCa was authorized by the Commission to implement a data processing personal health data for the purpose of creating dashboards and studying the trajectory of cancer patients using data from the SNIIRAM (National Health Insurance Inter-regime Information System) and the Program for the medicalization of information systems (PMSI), held by the National Health Insurance Fund (CNAM) (authorization request no. 911297). At the same time, the Commission notes that INCa, as a body entrusted with a public

service mission, has permanent access to all individual data from the National Health Data System (SNDS) with cross-referencing potential identifiers for the processing necessary to carry out its missions pursuant to Articles R. 1461-12 and R.1461-14 of the CSP. The historical depth of this permanent access is limited to nineteen years, in addition to the current year (article R. 1461-13 of the CSP). In order to use this data, INCa has set up a child system of the SNDS, as defined by the order of 22 March 2017 relating to the safety standards applicable to the SNDS. The Commission notes in this respect that the database currently used by INCa only includes data already available in the SNDS (SNIIRAM, PMSI, causes of death), and is intended to be supplemented with data from the other components of the SNDS as soon as these become available (data from the disability, data from supplementary insurance schemes). INCa also wishes to enrich its database with data from cancer registries as well as cancer screening management structures, in order to have quality information that is relevant from an epidemiological point of view. thus the aim is to produce dashboards aimed at evaluating cancer control systems (in particular cancer plans), to carry out expert appraisals at the request of the ministries on questions relating to oncology and to carry out observational studies relating to oncology as a whole. The Commission considers that the purpose of the processing is determined, explicit and legitimate, in accordance with Article 5 paragraph 1 point b) of the GDPR and that it presents a purpose of public interest, in accordance in article 66-I of the amended law of January 6, 1978 (hereinafter the Data Protection Act). The Commission notes that this database, which requires matching between SNDS data and data from cancer registries and cancer screening management structures, is not intended to carry out a research project specific but is similar to a data warehouse. Therefore, the creation of this warehouse, entitled Oncology data platform, must be authorized on the basis of the provisions of sub-section 1 of section 3 of chapter III of the Data Protection Act amended by Ordinance No. 2018-1125 of December 12, 2018 (Articles 65 and following of the Data Protection Act). The Commission recalls that the processing of personal health data which will be implemented subsequently, for the purposes of studies, research and evaluations in the field of health, are separate processing operations which must be subject to specific formalities. provided for in Articles 72 et seq. of the amended Data Protection Act. On the legality of the processing and the conditions for processing data concerning health The processing implemented by the data controller is intended to coordinate actions in the fight against cancer and is necessary for the performance of a mission of public interest entrusted to INCa. It is, as such, lawful under Article 6, paragraph 1 point e) and meets a condition allowing health data under Article 9(2)(i) of the General Data Protection Regulation (GDPR). On the data sources and the pairing envisaged With regard to data from the National Health Data System (SNDS) These are

data for which INCa has permanent access in accordance with Decree No. 2016-1871 of December 26, 2016 and pursuant to Article L. 1461-3-III of the Public Health Code. They must be limited to the scope authorized by this decree, in terms of the nature of the data and historical depth.

Concerning data from cancer registers Data from registers result from an exhaustive recording of people with cancer and newly diagnosed living in the territory covered by the register. The registers contain information relating to the identification of the type of cancer (topography, histology, stage at diagnosis, etc.), exposure factors, care, follow-up and the survival of people, as well as additional information on the health course or the impact of cancer (people's experiences, quality of life, use of specific care, etc.). The integration of this source of information into the current database aims to improve the precision and accuracy of the results of the treatments carried out, in particular by improving the precision of the information (confirmation of the organ of the primary cancer, stage to the diagnosis, histological type of cancer, laterality of the cancer or death of the persons, where applicable) and by providing additional information relating in particular to exposure and treatment.

evaluation by the Registry Evaluation Committee and having completed the appropriate formalities with the Commission must supply the INCa warehouse. The Commission requests that INCa inform it of any new registry intended to integrate the warehouse and which is not mentioned in the appendix to the document dated 4 September 2018 included in the file submitted to the Commission.

s screening management The screening management structures collect information relating to the level of risk of people in relation to the cancer screened, the health pathway (participation in screening actions, reason for refusal, etc.) and, where applicable, the course of care (elements of the diagnosis, first treatments, etc.). Finally, the Commission notes that the information transmitted by cancer registries and screening management structures will not include the surname and first name of individuals or their day of birth.

On the nature of the data processed The following categories of data will be collected: With regard to patients, gender, month and year of birth of the persons concerned, municipality of residence; medical, medico-social and medico-economic information relating to the health care pathway (including prevention, screening, diagnosis, hospital care, care, follow-up and after cancer); medico-social information relating to the situation of people with disabilities, subject to their availability in the SNDS; information relating to the place of residence, lifestyle, to professional life, to social disadvantage or which can contribute to the study of social and geographical inequalities and of an economic order; information relating to work stoppages and cash benefits; information relating to vital status and death (months and years, place and medical causes); information relating to compulsory health insurance organizations and, if applicable , to complementary health insurance organizations involved in the financial coverage

of the beneficiary of care and services. With regard to health professionals the month and year of birth, sex, places, methods of exercise, etc.; health services and (type, places, etc.) involved in the health journey of people. On the identification number of the people concerned (person code) and the planned matching of data For each data source, a unique code is assigned to each person by the organization at the origin of the production of the data and integrated into the warehouse. This code is different from the identification number used by the source organization in its databases. A correspondence table (not sent to INCa) is kept by the source organization and completed with each new delivery of data to INCa. Matching between the data in the current database and those from cancer registers or screening management structures will be done probabilistically using the following variables: gender, month and year of birth, municipality of residence; the year of diagnosis and possibly the consumption of care (for example chemotherapy or carrying out a test screening). A correspondence table specific to INCa will allow it to link the same individual to several data sources. The Commission considers that the data processed 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 paragraph 1 point c) of the GDPR. On the retention period of the data The data will be kept in the warehouse for a period of twenty years. The Commission considers that this period does not exceed the period necessary with regard to the purpose for which they are collected and processed, in accordance with the provisions of Article 5 paragraph 1 point e) of the GDPR. On the recipients of the data Only INCa has access to the data within the framework of this authorization. It keeps up-to-date documents indicating the competent person(s) within it to issue the authorization to access the data, the list of persons authorized to access this data, their respective access profiles and the methods of attribution, authorization management and control. Only persons authorized by the data controller may have access to the data. These categories of persons are subject to professional secrecy under the conditions defined by Articles 226-13 and 226-14 of the Criminal Code. The qualification of authorized persons and their rights must be regularly reassessed, in accordance with the methods described in the authorization procedure established by INCa. INCa for various research projects, studies or assessments. The Commission stresses that such an opening to new categories of recipients will require INCa to submit a request for modification of this authorisation. information of personsIn the case of persons whose data comes exclusively from the SNDS (unmatched)Information is produced in accordance with article R. 1461- 9 of the Public Health Code and Article 111 of the Data Protection Decree, i.e. on the website of health establishments, health insurance organizations or posters in premises open to the public or documents given to them. The Commission notes that INCa will also disseminate information relating to

this warehouse on its website. With regard to persons whose data will be collected from registers or screening management structures after this authorization (new patients or patients being monitored) In accordance with article 69 of the Data Protection Act, persons from whom personal data are collected or about whom such data are transmitted must make the object of individual information, including the elements provided for in Article 13 or 14 of the GDPR. The Commission notes that, insofar as INCa does not have either the identity or the address of the persons concerned, the information of the persons will be carried out concomitantly with the information of the persons carried out within the framework of: the constitution of the cancer registers; the treatments implemented by the screening management structures. Thus, the Commission notes that the persons concerned are informed individually by health professionals when their data is collected with a view to completing the cancer registers, as well as by the cancer screening management structures, through an individual information letter. The Commission notes that the information notes will mention INCa as the recipient of the data, the planned pairing with the SNDS data as well as a link to the website dedicated to the use of INCa data. The Commission requests that the reference to this processing, relating to the constitution of a warehouse, be explicitly added to these information media, as well as all the information provided for in Article 14 of the GDPR, with regard to the indirect collection of personal data. screening prior to this authorization The Commission notes, as mentioned above, that INCa does not have the identity and address of the persons concerned. It also notes that, given the number of persons concerned (approximately 7 million), uncertainty about their vital status and the age of some of the data, the data controller considers that individually informing all of the data subjects would require a disproportionate effort. Thus, in accordance with Article 14 paragraph 5 point b) of the GDPR, the data controller intends to take the following measures to protect the rights and freedoms as well as the legitimate interests of the persons concerned: On the one hand, INCa undertakes to make available on its website collective information relating to this repository as well as information on subsequent research projects carried out from the data it contains and including all the information provided for in Article 14 of the GDPR. On the other hand, it undertakes to implement information by means of posters in all the centers where the persons concerned are usually cared for (health establishments, centers for the fight against cancer, etc.), as well as during institutional information campaigns and through patient associations. Subject to taking these observations into account, the Commission considers that these information methods are satisfactory with regard to the provisions of the GDPR and the law computing and Freedom. On the rights of persons The persons concerned exercise their rights by directly contacting the data controllers of the organizations from which the data concerned are collected, in

accordance with the provisions applicable to each of them (SNDS, cancer registry or management structures of screenings). INCa facilitates the exercise of these rights by referring to these different structures when the person exercises their rights directly with it. The Commission considers that these procedures for exercising rights are satisfactory with regard to the provisions of the GDPR and the computing and Freedom . On data security and traceability of actions Regarding the transfer of data, these are transmitted in the form of encrypted files with state-of-the-art algorithms. The Commission recalls that the key management algorithms and procedures must comply with appendix B1 of the general security reference system of the National Agency for Information Systems Security (ANSSI). The Commission takes note of the approval decision issued on 17 May 2019 in accordance with the security baseline applicable to the SNDS set by the decree of 22 March 2017 including the data protection impact analysis (DPIA), the risks residuals and the action plan identified and accepted by the controller. The Commission recommends implementing the measures intended to improve traceability and alerts as soon as possible, and in the meantime, carrying out regular manual monitoring. Subject to the previous observations, the security measures described by the person in charge of processing comply with the security requirements provided for in Articles 5.1.f and 32 of the General Data Protection Regulation, as well as with the security reference framework applicable to the SNDS appended to the order of 22 March 2017. The Commission nevertheless recalls that this obligation requires the regular updating of the security measures, the impact analysis relating to privacy as well as the security accreditation with regard to the regular reassessment of the risks. Under these conditions, the Commission authorizes the National Cancer Institute to implement automated processing of personal data for the purpose of setting up a health data warehouse aimed at studying the trajectories of people with cancer, entitled: Oncology data platform. President Marie-Laure DENIS