Deliberation 2020-127 of December 10, 2020 National Commission for Computing and Liberties Nature of the deliberation: Authorization Legal status: In force Date of publication on Légifrance: Wednesday August 25, 2021 Deliberation n° 2020-127 of December 10, 2020 authorizing the cancer (INCa) and the company AstraZeneca to implement automated processing of personal data for the purpose of a study entitled "ATU PACIFIC and Cancer Data Platform", relating to the longitudinal follow-up of patients with cancer of the Inoperable stage III non-small cell lung (NSCLC) treated with durvalumab after chemoradiotherapy. (Request for authorization no. 919440V1) The National Commission for Computing and Liberties, Seizure by the National Cancer Institute (INCa) and the company AstraZeneca of a request for authorization concerning the automated processing of personal data personnel whose purpose is a study entitled ATU PACIFIC and Cancer Data Platform relating to the longitudinal follow-up of patients with inoperable stage III non-small cell lung cancer (NSCLC) treated with durvalumab after chemoradiotherapy; Convention No. 108 of the Council of Europe for the protection of individuals with regard to automatic processing of personal data; Having regard to Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 relating to the protection of individuals with regard to the processing of personal data and the free movement of such data, and repealing Directive 95/46/EC; Having regard to the Public Health Code, no. in particular its articles L. 1461-1 and following; Having regard to law n° 78-17 of January 6, 1978 as amended relating to data processing, files and freedoms, in particular its articles 66, 72 and following; Having regard to decree n° 2019-536 of May 29, 2019 taken for the application of law n ° 78-17 of January 6, 1978 relating to data processing, files and freedoms; Having regard to the decree of March 22, 2017 relating to the applicable security reference system to the national health data system; Having regard to the favorable opinion with recommendations of the Ethics and Scientific Committee for research, studies and evaluations in the field of health of October 4, 2019; Having regard to deliberation no. 2019-082 of 20 June 2019 authorizing the National Cancer Institute (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: Cancer data platform;V u deliberation no. 2019-083 of June 20, 2019 issuing a single decision and authorizing the National Cancer Institute (INCa) to implement automated processing for research, study and evaluation purposes based on the Platform oncology data from INCa; Considering the file and its supplements; On the proposal of Mrs Valérie PEUGEOT, Commissioner, and after having heard the observations of Mr Benjamin TOUZANNE, Government Commissioner, Formulates the following observations: On the persons responsible The two data controllers, the National Cancer Institute (INCa) and Astra Zeneca jointly determine the purposes and means of the

processing. In this respect, the Commission recalls that, in accordance with Article 26 of the GDPR, the joint controllers must define their respective obligations in a transparent manner. It notes that the distribution of roles and responsibilities has been formalized by an agreement between the two parties. On the use of INCa's Cancerology Data Platform The Commission notes that the processing requires the use of data from the oncology data, for which INCa has authorization (deliberation no. 2019-082 of June 20, 2019 - authorization request no. 918314). This platform includes data from: the National Health Data System (SNDS) to which INCa has permanent access, in accordance with the provisions of Articles R. 1461-11 et seq. of the Public Health Code; of cancer; cancer screening management structures. and the hospital federations and, on the other hand, carries out pre-processing specific to the field of oncology. The Commission thus takes note of the specificity of the data appearing within the Cancerology Data Platform, which are necessary for this study. On the application of the provisions related to the SNDS The processing of data from the National Health Data System and its components must be carried out in accordance with the provisions of Articles L. 1461-1 to L. 1461- 7 of the Public Health Code, in particular with regard to the prohibition on using this data for prohibited purposes. The Commission notes that the company Astra Zeneca, as a person producing or marketing the products mentioned in II of the article L. 5311-1 of the public health code, is required, in accordance with II of article L. 1461-3 of the public health code: either to demonstrate that the methods of implementation of the processing make any use of the data for one of the purposes mentioned in V of Article L. 1461-1; either to use a research laboratory or a design office, public or private, to carry out the processing. species, it notes that, in accordance with deliberation no. 2019-082, only INCa will have access to data from the Cancer Data Platform. Thus, AstraZeneca will at no time have access to data from the SNDS. The Commission also notes that only aggregated and anonymous data will be sent to it and that this condition is formalized in the agreement concluded between INCa and the company AstraZeneca. The Commission considers that these guarantees are such as to demonstrate that the methods of implementation of the processing render impossible any use of the data for one of the prohibited purposes mentioned in Article L. 1461-1 of the CSP and in particular in this case for the purposes of promoting the products mentioned in II of Article L. 5311-1 aimed at healthcare professionals and healthcare establishments. On the legality of the processing This processing, carried out for the purposes of scientific research, is necessary for the performance of a public interest mission entrusted to the INCa and for the purposes of the legitimate interests pursued by Astra Zeneca. The processing is therefore lawful with regard to Articles 6 paragraph 1 point f) and 9 paragraph 2 point j) of the GDPR. On the purpose and the public interest of the processingThe Commission notes that

this study is being conducted within the framework of the strategic contract for the health industries sector signed between the health industries and the State on February 4, 2019. This contract records the completion of a pilot project led by the Alliance for Research and Innovation in Health Industries (ARIIS) and INCa to enhance public data by adding private data for projects in the public interest in the field of cancerology. The present study is one of the proofs of concept of the pilot project. The purpose of the processing is to implement a study on the longitudinal follow-up, using the Cancer Data Platform, of patients with inoperable stage III non-small cell lung cancer (NSCLC) treated with durvalumab after chemoradiotherapy under a temporary authorization for use (ATU) and aims in particular to contribute to: validating data matching capabilities collected within the framework of an ATU by the laboratory, to medico-administrative data and to establish the specificities specific to each source; the optimization of the collection of data during ATU; the improvement of knowledge on the course of the people affected of this cancer and on the care offered to them; the definition of a standardized data set that can be applied in future studies on ATUs related to oncology. considers that the purpose of the processing is determined, explicit and legitimate, in accordance with Article 5.1, b) of the GDPR. It also considers that this processing serves a purpose of public interest, in accordance with Article 66 -I of the Data Protection Act. On the nature of the data processed The data from the INCA's Cancerology Data Platform (authorization request no. 918314) will be reused in the context of this study and will be matched with certain data from the following processing operations, having the subject of the appropriate formalities: data from the PACIFIC R study, for which the data controller is Astra Zeneca (345 patients from 63 different centres); data from the cohort ATU, for which the data controller is Astra Zeneca (246 patients in 170 centers). The Commission considers that the data whose processing is envisaged 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. the rights of individuals, transparency and the publication of resultsOn the information of individualsAs regards data from the PACIFIC R study: The heads of the investigation centers, which have the contact details of the people concerned, have indicated to the processing managers be in a position, in the context of the current health crisis, to provide them with individual information. The Commission notes, however, that the individual information note sent to the people included in the PACIFIC R study mentioned the possibility of reusing the study for the purposes of subsequent research as well as a possible matching of this data with the SNDS. The Commission however asks that the persons be individually informed of the study when the health context allows. With regard to cohort ATU data: The Committee notes that the individual information of the persons concerned initially planned cannot be

carried out with patients who are no longer followed due to the health crisis. However, it asks that the people being monitored be individually informed of the study. On the appropriate measures Pursuant to Article 14-5-b of the GDPR and Article 69 of the amended Data Protection Act, the obligation to inform the data subject individually may be subject to exceptions in the event that the provision of such information proves impossible, would require disproportionate effort or would seriously compromise the achievement of the processing objectives. In such cases , in accordance with the General Data Protection Regulation, 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. The Commission acknowledges that appropriate measures will be implemented, in particular by: the dissemination on the website of the two data controllers of information r relating to the research project including all of the information provided for in Article 14 of the General Data Protection Regulation; the display of information specific to the study in all the participating centers. On the transparency of resultsThe Commission notes that the data controller plans to make public the matching and data processing methods as well as the decision-making algorithms that will be developed. It also notes the commitment of data controllers to ensure that the results of the work are systematically published. It recalls that, when the result of the data processing is made public, the direct or indirect identification of the persons concerned must be impossible, in accordance in article 68 of the Data Protection Act. On security measures and traceability of actions The Commission recalls that security measures must meet the requirements provided for in Articles 5-1-f) and 32 of the General Data Protection Regulation. They must also comply with the safety baseline applicable to the SNDS set by the order of 22 March 2017. The Commission notes that a probabilistic matching between data from the cancerology data platform and data from studies of Astra Zeneca, will be produced by INCa from previously determined variables. To do this, it notes that the data will be transmitted by the company Astra Zeneca to INCa in the form of files encrypted with algorithms and key management procedures in accordance with appendix B1 of the general security reference system. The Commission notes that a correspondence table is kept by the company Astra Zeneca and recalls that the methods for its conservation must be subject to appropriate technical and organizational measures. The Commission notes that the matching and analysis of the data will be carried out on the INCa oncology data platform and takes note of the decision to approval of this Platform pronounced on April 27, 2020 for a period of two years, including the data protection impact analysis (DPIA), the residual risks and the action plan identified and accepted by the data controller The Commission points out that, following the recommendations issued in its deliberation No. 2019-083 of June 20, 2019, complete

and saved traces have been put in place, associated with a system of strong authentication, bastion and virtual office. It also notes that external accesses to the platform have been subject to a security audit and corrective measures. security events (SIEM) was launched, with a view to its implementation within two years. It notes that, pending this deadline, the system logs are the subject of a weekly manual analysis and that the exports of aggregated data are monitored monthly by an operator with a keyword detection system. In this respect, it recommends formalizing a procedure for reporting alerts and managing incidents. security measures. In accordance with the SNDS security reference system, only anonymous data may be exported outside an approved environment. In this respect, the Commission recalls that the data controller must carry out an analysis to demonstrate that its anonymization processes comply with the three criteria defined by Opinion No. 05/2014 on anonymization techniques adopted by the Article 29 (G29) on April 10, 2014. Failing this, if these three criteria cannot be met, a study of the risks of re-identification must be carried out. On the retention period of the data The data will be kept for five years. This duration does not exceed that necessary for the purposes for which the data is collected and processed, in accordance with the provisions of Article 5-1-e of the GDPR. the Cancer Data Platform will require, subject to authorization by the Commission, a modification of the authorization issued to INCa (deliberation no. 2019-082). Authorizes, THE NATIONAL CANCER INSTITUTE (INCA) AND THE AST COMPANY RA ZENECA in accordance with this deliberation, to jointly implement the aforementioned processing.The PresidentMarie-Laure DENIS