Deliberation 2022-063 of May 23, 2022 National Commission for Computing and Liberties Nature of the deliberation: Authorization Legal status: In force Date of publication on Légifrance: Friday June 17, 2022 Deliberation n° 2022-063 of May 23, 2022 authorizing the AGORIA SANTE consortium composed companies Docaposte, AstraZeneca and Impact Healthcare to implement automated processing of personal data for the purpose of setting up a health data warehouse, called “Agoria Health Platform”. (request for authorization no. 2225091) The National Commission for Computing and Liberties, Seizure by the companies Docaposte, AstraZeneca and Impact Healthcare of a request for authorization concerning the automated processing of personal data for the purpose of constitution of a health data warehouse called Agoria Health Platform; Having regard to Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 on the protection of individuals with regard to the processing of personal data personnel and the free movement of such data, and repealing Directive 95/46/EC (RGPD); Having regard to Law No. 78-17 of 6 January 1978 as amended relating to data processing, files and freedoms and freedoms), in particular its articles 44-3° and 66; After having heard the report of Mrs Valérie PEUGEOT, commissioner, and the observations of Mr Benjamin TOUZANNE, commissioner of the Government; On the data controllers: Several bodies isms act as joint data controllers within the framework of the constitution of the warehouse called Agoria Health Platform: the company AstraZeneca France, a subsidiary of the international pharmaceutical group AstraZeneca, which produces and markets the products mentioned in II of Article L 5311-1 of the Public Health Code (CSP); the company Impact Healthcare; the company Docaposte BPO, digital subsidiary of the La Poste group, which is responsible for hosting the data contained in the warehouse and has been , as such, qualified as trusted third parties. These three companies, brought together in a consortium that does not have legal personality, jointly define the purpose and means of the processing implemented as part of the constitution of the Agoria Santé platform, as joint controllers, within the meaning of Article 26 of the General Data Protection Regulation (GDPR). As such, they must transparently define their respective obligations under the consortium contract that binds them. The modification of the composition of the consortium would constitute a substantial modification of the data processing and would require the filing of a request for modification of the data. authorization. On the purpose of the processing, its lawfulness and the conditions for processing data concerning health: The joint data controllers wish to set up a health data warehouse in order to allow research, studies or assessments in the field of health intended in particular to: describe the conditions of use of health products in everyday practice as part of the care pathway; measure the effectiveness and risks associated with the use of a therapy (drug , medical device, digital solution, etc.); measure the

organizational impact of a health product; measure resource consumption urces and the medico-economic performance of a therapy in real life. processing involving data relating to health and justified, as in this case, by the public interest This warehouse will initially be fed with personal data from: the medical files of patients receiving medicines dispensed in the framework of three early access authorizations operated by the company AstraZeneca France; of the National Health Data System (SNDS) for the people included in these cohorts. The purpose of the processing is determined, explicit and legitimate, in accordance with the provisions of the Article 5-1-b) of the GDPR. The processing implemented by the joint controllers is necessary for the purposes of the legitimate interests they pursue. This processing is, as such, lawful under Article 6-1-f) of the GDPR and fulfills a condition allowing the processing of data concerning health under the provisions of Articles 9-2-j) of the GDPR and 44-3 of the Data Protection Act. The constitution of the Agoria Santé platform requires matching between data from the SNDS and the three processing operations resulting from the therapeutic use and data collection protocols. The data contained in this warehouse cannot , in accordance with the provisions of Article L. 1461-1 of the CSP, be used for the purpose of promoting health products to health professionals or health establishments, or for the purpose of excluding guarantees of insurance contracts and modification of insurance contributions or premiums for an individual or a group of individuals presenting the same risk (prohibited purposes of using the SNDS) Similarly, the Commission recalls the prohibition to constitute and of ut use, for prospecting or commercial promotion purposes, files composed from data directly or indirectly derived from medical prescriptions, as soon as these files make it possible to directly or indirectly identify the prescriber (article L. 4113-7 of the code of public health). With regard to the constitution of the Agoria health platform, the contract concluded between the three joint data controllers provides that: the status of member of the consortium does not confer any right of access to the SNDS data contained in the warehouse; only the member of the consortium designated as trusted third party (Docaposte) has access to SNDS data in compliance with the missions entrusted to it. With regard to reuse for research purposes , studies or assessments in the field of health, the Commission notes that a contract will be systematically concluded with each body (hereafter the project promoters), whether it is be a member or not of the consortium, wishing to process the data contained within the Agoria platform for the purposes of research, studies or evaluations in the field of health. The draft contract provides for the systematic use of a laboratory of research or to a design office to implement data processing when the project leader produces or markets products mentioned in II of article L. 5311-1 of the CSP or is mentioned in 1° of A and in 1°, 2°, 3°, 5° and 6° of B of I of Article L. 612-2 of the Monetary and Financial Code or is an insurance intermediary

mentioned in Article L. 511-1 of Insurance Code.Finally, 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 require that each research project, study or evaluation be justified. by the public interest and be subject to proper formalities. warehouse governance: The Agoria Santé consortium has set up a governance system for the Agoria Santé platform consisting of: a steering committee responsible for making strategic decisions relating to the overall management of the warehouse, which can rule on:
the progress of the Agoria program (which includes the deployment of the Agoria health platform); the strategic and scientific orientation of the program, if necessary on the proposal of the monitoring committee; the consortium's budget; the entry of a new member in the consortium; the exclusion of a member; the principle and content of publications and communications relating to the Agoria Santé program; an operational committee implementing the objectives and decisions taken by the steering committee, responsible in particular:
coordinate the conduct of projects allowing the application of the strategic and scientific orientations of the Agoria Santé program defined by the steering committee, taking into account the opinions and recommendations of the monitoring committee; keep a general roadmap of the program updated at each meeting the operational committee; an ethics and scientific committee with an advisory role, whose missions are in particular to:
propose changes to the program to the steering committee; produce opinions on the scientific, ethical and technical orientations decided by the steering committee; inform the steering committee about any difficulties encountered in carrying out the program; arbitrate, if necessary where appropriate, with regard to questions relating to the lawfulness of the processing envisaged by the project leaders when they are producers of health products or health insurers and in particular to verify that the projects do not pursue one of the prohibited purposes referred to by V of article L. 1461-1 of the CSP for access to SNDS data. These governance committees are notably composed of qualified members in terms of SNDS data processing. of the Agoria Santé platform come from three processing operations of personal data collected within the framework of protocols for therapeutic use and collection of data from early access (PUT-RD), placed under the responsibility of AstraZeneca: data from the Forxiga 10 mg early access program in the indication of chronic kidney disease in adults:
administrative identification data: patient identification number assigned as part of early access; health data:
demographic data: date of birth, sex, weight, height; diagnosis and condition of the patient: date of diagnosis of kidney disease (month/year), etiology of kidney disease; previous treatments, comorbidity; data from biological examinations; data relating to

treatment: dosage, duration, concomitant treatments and/or supportive care, interruption; data relating to the monitoring of adverse effects, reasons for stopping treatment. PUT-RD of data from the Lynparza 100 mg early access program and Lynparza 150 mg for adjuvant treatment of adult patients with HER2-negative high-risk early breast cancer with a BRCA mutation who have previously been treated with neoadjuvant or adjuvant chemotherapy:

administrative identification data: patient identification number assigned as part of early access; health data:

demographic data: date of birth, gender, weight, height; patient diagnosis and condition: date of initial diagnosis of breast cancer, current stage, TNM classification at current stage and at diagnosis, type of breast cancer, histology, ECOG status current, BRCA ½ gene mutation; data relating to procreation: effective method of contraception in women of childbearing age, pregnancy test, partner of childbearing age; previous treatments, comorbidity; biological examination data; therapeutic treatment: dosage, duration, concomitant treatments and/or supportive care, interruption; data relating to the monitoring of adverse effects, reasons for stopping treatment. data from the patient's self-administered quality of life questionnaire. PUT-RD data from the Tixagevimab 150 mg and Cilgavimab 150 mg early access program for pre-exposure prophylaxis of COVID-19 in patients aged twelve years and older:

administrative identification data: patient identification number assigned as part of early access; health data:

demographic data: date of birth, sex, weight, height; diagnosis and condition of the patient: virological status on inclusion (nasopharyngeal RT-qPCR test for diagnosis of SARS-CoV-2 infection), immunological status on inclusion (level of anti-S antibodies); previous treatments (history of vaccination against COVID-19 and history of treatment with a combination of monoclonal antibodies), comorbidities (risk factors for developing a severe form of COVID-19 and medical history); data from biological examinations: quantitative serology (search for antibodies, search for SARS-CoV-2 infection, virological test for detection of SARS-CoV-2, sequencing of the viral strain and search for mutations), in the event of a positive SARS-CoV-2 virological test since the last visit: symptomatology of COVID-19, oxygen therapy, hospitalization, other treatments used in the management of COVID-19, intensive care/resuscitation unit ;survival data ;tolerance data;follow-up of adverse effects/special situations including pregnancy.The patient identifier present in the source data is replaced by a new identifier generated randomly when they are integrated into the Agoria Santé platform. The Commission recommends that this new identifier be generated by a cryptographic hash function resistant to brute force attacks or by a cryptographically secure pseudo-random number generator. SNDS within the framework of the Agoria Santé platform: Data from the Agoria Santé platform will be

matched with certain data from the SNDS relating to people participating in the three early access cohorts concerned, and coming from: the National inter-regime information system Health Insurance (SNIIRAM); the Information Systems Medicalization Program (PMSI); the Center for Epidemiology on the Medical Causes of Death (CépiDC); the database relating to the screening of cases of covid- 19, called SI-DEP; from the database relating to vaccinations against covid-19, called Vaccin-covid. Data from SNIIRAM, PMSI and CépiDc for the years 2017 to 202 7 made available by the National Health Insurance Fund (CNAM) will feed the Agoria Santé platform for the purpose of implementing the passive monitoring of data subjects. The joint controllers also wish to enrich the Agoria Santé platform with certain data from SI-DEP and Vaccin-COVID databases collected from their constitution and until the year 2027. These data may only be made available subject, on the one hand, to the legislative and regulatory provisions applicable to this processing allowing it and, on the other hand, that they be disseminated by the CNAM. The joint data controllers transmitted, in support of their request, several expressions of SNDS needs specifying, for each early access cohort, the data of the SNDS intended to feed the Agoria health platform. Matching will be carried out in a probabilistic and iterative manner using common variables (for example, year of birth). e, sex, date of care, FINESS code of the place of treatment). Only the common matching variables will be transmitted to the CNAM for the extraction of data from the SNDS. The Commission recommends, in order to limit the risks of indirect re-identification, not to use the internal identifier of the Agoria Santé platform in this shipment and to replace it with a temporary random identifier, the correspondence table of which will be logically separated from the data of the warehouse. 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. On the retention period of the data: The data will be kept in an active database for a period of ten years. Beyond that, the data will be anonymized or deleted. These data retention periods do not exceed the periods necessary for the purposes for which they are collected and processed, in accordance with the provisions of Article 5-1-e) of the GDPR. On the accessors and recipients of the data: Only Docaposte (in its capacity as a trusted third-party member of the consortium) and the persons authorized by it have access to the data in the context of the implementation of this processing. 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, management and control of authorizations. These categories of persons are subject to professional secrecy under the conditions defined by articles 226-13 and 226-14 of the penal code. The qualification of authorized persons

and their access rights must be regularly reassessed, in accordance with the procedures described in the authorization procedure established by Docaposte. Any change of trusted third-party member would constitute a substantial modification of the data processing given its capacity as manager of the SNDS child system. Health establishments, institutes or research centers, health cooperation groups, public interest groups, manufacturers of e health products (drugs, medical devices, etc.), cosmetics manufacturers, groups of pharmacies or companies supporting health players may, after the agreement of the governance committees of the Agoria health platform and the completion of the prior formalities provided for by the Data Protection Act, implement research projects based on data from the warehouse. On the information of people: The three early access cohorts being placed under the responsibility of AstraZeneca , the persons concerned will be individually informed by the latter of the processing of data concerning them within the framework of the constitution of the Agoria Santé platform. This information note must be completed in order to include all the information provided for in Article 14 of the GDPR. A transparency portal on which the information note relating to the constitution of the warehouse, as well as on the various information notes relating to future research carried out using data from the warehouse will be available on a website dedicated to the Agoria health platform. The results of these research projects will be published on this transparency portal. Article L. 1461-3 of the CSP makes access to data from the SNDS and its components subject to communication to the Health Data Platform (PDS) of several elements by the data controllers, before and after the studies. Research, study or evaluation projects carried out using data from the Agoria Santé platform must be registered in the public directory of the PDS. The Commission recommends that the warehouse also be registered in the public directory of the PDS. Finally, the Commission asks that it be sent to it every three years a report on the operation of the warehouse and on the research carried out on the basis of the data it contains.These terms and conditions comply with the principle of transparency and the information requirements provided for in Articles 12 and following of the GDPR.On the rights of data subjects:All the rights of data subjects are exercised with the Data Protection Officer. of the data of the Agoria Santé consortium. In the event of exercise of the right of opposition, the data of the person concerned will not be fed into the warehouse or will, if necessary, be deleted. On the absence of transfer of data and the use of a subcontractor exclusively subject to the laws and jurisdictions of the European Union: The establishment of this warehouse does not result in the transfer of personal data, directly or indirectly id entifiantes, outside the European Union. In addition, the health data is stored within a certified host for the hosting of health data, located in France and exclusively subject to the laws and jurisdictions of the European Union .On data security and traceability of

actions: The data controller has carried out and transmitted in support of the authorization request an impact analysis relating to data protection specific to the creation of the Agoria Santé platform , as well as a risk analysis on the security of information systems.An approval was carried out by the approval authority on April 29, 2022 in accordance with the decree of March 22, 2017 relating to the security reference system applicable to the System national health data. The Commission notes that a new approval commission is scheduled for May 30, 2022 to take into account the update of the risk analysis and the associated treatment plan, following the latest developments related to the construction of the warehouse. .In this respect, the Commission recommends that the implementation of tools and procedures for the protection of cryptographic secrets, technical logging and traceability of actions, and incident detection and management, be finalized before the implementation of the processing. .Health data will be stored with a host certified for hosting health data. Data will be encrypted at rest and in transit to external systems, in compliance with the recommendations of the National Information Systems Security Agency. Technical and organizational measures will be implemented to partition the different data sets. The warehouse containing the source data from the cohorts and the SNDS will only be accessible by Docaposte, in its capacity as data host for the Agoria Santé platform. Administrator access will be secured and traced through an administration bastion. Docaposte will also be the only one to have access to the space for preparing data extracted from the warehouse to be made available to a research. During the preparation phase, the data will be standardized, normalized and again pseudonymized, or even anonymized. The data will then be placed in a workspace specific to each research project, to which only the data controller (or, if applicable , the research laboratory or the design office) will have access, isolated from other spaces by software containerization solutions. This workspace will thus contain only the data necessary for the project, with a randomly generated identifier that will be specific to each project. In this respect, the Commission recommends the use of a cryptographically secure pseudo-random number generator. The data life cycle management mechanisms will be automated, in order to manage the retention periods of the source data (cohort data and of the SNDS) and data from the project spaces. The purging systems will be automated and a tracking of retention periods by source database will be made available in the service catalog. The security measures described meet the requirements of Articles 5.1, f) and 32 of the GDPR taking risks identified by the joint controllers. It will be up to the latter to carry out a regular reassessment of the risks for the persons concerned and an update, if necessary, of these security measures. Under these conditions, the Commission authorizes the AGORIA SANTE consortium made up of the companies Docaposte, AstraZeneca and Impact Healthcare, to implement personal data processing for the purpose of setting

up a health data warehouse called the Agoria health platform for a period of ten years. President Marie-Laure DENIS