Deliberation 2023-042 of April 27, 2023 National Commission for Computing and Liberties Nature of the deliberation: Other authorization Legal status: In force Date of publication on Légifrance: Friday May 05, 2023 Deliberation n° 2023-042 of April 27, 2023 authorizing the company Clinityx to implement automated processing of personal data for the purpose of a study on the consumption in France of originators and anti-TNF alpha biosimilars, entitled "Magellan Anti-TNF alpha". (Request for authorization no. 923011)

The Commission Nationale de l'Informatique et des Libertés, Seizure by the company Clinityx of a request for authorization concerning the automated processing of personal data for the purpose of a study on the consumption in France of originators and anti-TNF biosimilars alpha, entitled "Magellan Anti-TNF alpha"; 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 and on the the free movement of such data, and repealing Directive 95/46/EC (general regulation on data protection); 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 the favorable opinion of the Ethics and Scientific Committee for research, studies and evaluations in the field of health of January 12, 2023; Having regard to the file and its supplements; On the proposal by Mrs Valérie PEUGEOT, commissioner, and after having heard the observations of Mr Benjamin TOUZANNE, government commissioner, Makes the following observations: On the data controller The company Clinityx is a consulting firm which carries out research in the field of health, in particular based on data from the National Health Data System (SNDS). It develops tools to enable the use of health data. On the purpose of the processing and its nature in the public interest The purpose of the processing envisaged is to carry out a study entitled "Magellan Anti-TNF alpha" intended to: describe the consumption in France of anti-TNF alpha originators and biosimilars; describe the consumption of anti-TNF alpha biosimilars by indication; describe the demographic characteristics of patients treated with anti-TNF alpha and biosimilars; quantify the conversions between originators and biosimilars and between the different biosimilars; measure the share of initiation of a biosimilar and of conversion originator to biosimilar following consultation with a specialist practitioner. The purpose of the processing is determined, explicit and legitimate, in accordance with article 5.1.b of the regulation general on data protection (RGPD), and this processing has a purpose of public interest, in accordance with article 66. I of law n ° 78-17 of January 6, 1978 modified (law "data processing and freedoms") .On the legality of the processing and the conditions allowing the processing of data concerning healthThe processing implemented by the company Clinityx is necessary for the purposes of

the legitimate interests that it pursues.This processing is, as such, lawful with regard to the GDPR Article 6.1.f. In addition, this processing, necessary for scientific research purposes, also fulfills the condition provided for in Article 9.2.j of the GDPR allowing the processing of data concerning health. This research project is subject to the provisions of Articles 44.3°, 66.III and 72 and following of the amended law of January 6, 1978, which provide, in the absence of compliance with a reference methodology, that processing for the purposes of research, study or evaluation in the field can only be implemented after authorization from the Commission. On the reuse of data from an existing database The data reused in the context of this study will come from the health data warehouse called "Magellan" ( deliberation n° 2022-009 of January 27, 2022). This warehouse is fed by a determined and limited number of variables from the SNDS, over a data depth of five rolling years. During each data update, the oldest data is anonymized or deleted. The data from this health data warehouse feeds the "Magellan" tool intended to automatically calculate predetermined public health indicators relating to patient populations, the use of care and the use of health products. On the application of the provisions relating to the SNDSThe Commission recalls that all the legislative and regulatory provisions relating to the SNDS are applicable in this case, and in particular the ban on using this data for the purposes described in Article L. 1461-1 V of the Public Health Code (CSP). On the special categories of data processed The data processed, which will come exclusively from the "Magellan "composed exclusively of data from the SNDS, are described in the application file and will concern: the patients (long-term condition, age and gender); their hospitalizations (main and associated diagnosis, procedures performed, type of establishment); their pathways care (medication consumption in town, consultations with a healthcare professional, procedures reimbursed in town). processing, in accordance with the provisions of Article 5.1.c of the GDPR.On information and the rights of individualsAs regards the methods of information:The Commission recalls that the provisions of Article 69 of the "Informatique et Libertés" law "are applicable to all processing carried out using SNDS data. In accordance with the provisions of Article 14 of the GDPR, in the event that the provision of individual information proves impossible, requires disproportionate effort or seriously compromises the achievement of the processing objectives, appropriate measures must be implemented by the data controller in order to protect the rights and freedoms, as well as the legitimate interests of the person concerned, including by making the information publicly available. In this case, an exception will be made to the principle of individual information of persons and appropriate measures will be implemented by the data controller to make the information publicly available concerning the performance of this study. The processing will be recorded within the transparency portal of the Health Data Platform. An

information note will also be made public within the transparency portal dedicated to the "Magellan" warehouse (via the "Semaphore" tool). set up by the controller. It must include all of the information provided for in Article 14 of the GDPR. Regarding the procedures for exercising rights: The persons concerned may exercise their rights with the data protection officer of the company Clinityx throughout the duration of the study.The Commission considers that these methods of information and exercise of rights are satisfactory with regard to the provisions of the GDPR and the law "Informatique et Libertés".On users and recipientsOnly the company Clinityx, responsible for the processing and the persons authorized by it, have access to the data within the framework of the implementation of this processing. Clinityx maintains 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 Criminal 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 the data controller. On the security measures and the traceability of actions The technical infrastructure of the company Clinityx in charge of the implementation of the "Magellan" warehouse , used for hosting child systems of the SNDS, has been analyzed by the Commission on various occasions, particularly in the context of previous authorization requests. authorization an impact analysis relating to data protection specific to the "Magellan" warehouse and to the various project spaces containing the studies related to this tool for producing indicators, as well as a risk analysis on the security of the systems information. An approval of the secure bubble was carried out by the approval authority on January 31, 2023, in accordance with the decree of March 22, 2017 relating to the security reference system applicable to the SNDS. This approval decision is only valid until December 31, 2024 and must therefore be renewed before this date if the project is still in progress. Technical and organizational measures have been planned by the data controller in order to partition the different extractions of data from the SNDS that can be stored within its technical solution. Separate environments, based on software containerization solutions, are implemented in particular to prevent any data merger. The query tool, the data handled by this tool, as well as the project spaces containing the data used to produce the indicators will be partitioned between them thanks to the use of these solutions. The Commission notes that access to the query tool and the project spaces of this study will only be possible for specifically authorized persons who are part of the staff of the company Clinityx, to the exclusion of any other outside person.

The Commission recalls that technical and organizational measures will have to be implemented in the technical solution in order to differentiate the personnel who can access the database of the "Magellan" warehouse containing the extraction of data from the SNDS on which the query tool and those that can only access the minimized data contained in the project spaces. The export of data out of the "Magellan" warehouse and the associated project spaces will consist exclusively of statistical reports including anonymous indicators that do not allow any re-identification of persons, and which will be transmitted exclusively to data controllers following requests made via the Magellan tool. To this end, a minimum threshold of eleven individuals will be retained for each aggregation. 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 group (G29) on April 10, 2014. If these three criteria cannot be met, an in-depth analysis of the identification risks must be carried out by the data controller in order to demonstrate that the latter, with reasonable means, are non-existent. The measures described 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 latter to carry out a regular reassessment of the risks for the persons concerned and an update, if necessary, of these security measures. On data transfers outside the European Union No transfer of data outside of the European Union will be carried out within the framework of this study. On the duration of data retention The data necessary for the realization of the requests will be kept in the workspace for the duration necessary for the production of the indicators and deleted in a maximum period of one month. The analyzes will be carried out annually for ten years, via the query tool, in the project space of this study. The Commission considers that this data retention period does 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. Authorizes, in accordance with this deliberation, the company Clinityx to implement the aforementioned processing.

The PresidentMarie-Laure DENIS