DELIBERATION n°2019-022 of FEBRUARY 28, 2019National Commission for Computing and FreedomsNature of the deliberation: AuthorizationLegal status: In force authorizing the company IQVIA Operations France to implement automated processing for research, study and evaluation purposes requiring access to national data from the program for the medicalization of information systems (PMSI) (Request No. 918351) The National Commission for Computing and Liberties, Seizure by the company IQVIA Operations France of a request for authorization of automated processing for research, study and evaluation purposes requiring access to national data from the medicalization of information systems; Having regard to Convention No. 108 of the Council of Europe for the protection of individuals with regard to automatic processing of data of a personal nature; 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; Having regard to the Public Health Code, in particular its articles L.6113-7 and L.6113-8; Having regard to Law No. 78-17 of 6 January 1978 as amended relating to the data processing, files and freedoms, in particular its articles 8-II-8°, 54, 61 and following; Having regard to Decree No. 2005-1309 of October 20, 2005 as amended, taken for the application of Law No. 78-17 of January 6, 1978 relating to data processing, files and freedoms; Having regard to Decree No. 2016-1871 of December 26, 2016 relating to the processing of personal data called "National Health Data System"; Having regard to the decree of March 22, 2017 relating to the security reference system applicable to the National Health Data System; Having regard to the opinion of the Expert Committee for research, studies and assessments in the field of health of October 3, 2018; After hearing Mrs. Valérie PEUGEOT, Commissioner, in her report, and Mrs. Nacima BELKACEM, Government Commissioner , in its observations, Makes the following observations: The National Commission for Computing and Liberties (hereinafter "the Commission") was seized on October 10, 2018 by the company IQVIA Operations France (hereinafter "the company IQVIA "), acting as data controller, of an application for authorization of automated processing for research, study and evaluation purposes requiring access to data from the program for the medicalization of information systems (PMSI ) through the secure access provider designated by the Technical Agency for Hospitalization Information (ATIH) platform, the Secure Data Access Center (CASD). organization” (CRO) o In French, "contract research organization", IQVIA Operations France is called upon by pharmaceutical companies to supervise and plan the conduct of clinical trials. This supervision notably requires selecting the countries and then the establishments in which the research will take place. In order to refine its strategy of targeting the French healthcare establishments most likely to host certain clinical trials, IQVIA wishes to

implement several hundred PMSI data processing operations annually. To do this, it has submitted to the Commission a request for authorization based on Article 54 of Law No. 78-17 of January 6, 1978 as amended (hereinafter "Data Protection Act"). The processing described falls under the processing authorization regime for research, study or evaluation purposes. The Commission considered it appropriate, given the information presented in the application file, and in particular the volume of processing envisaged, to authorize its implementation on the basis of the provisions of Articles 54 IV and 61 et seq. "computing and freedoms", within the framework of a single decision. On the application of the provisions related to the SNDS: Since the PMSI data comes from a component of the National Health Data System (hereinafter "SNDS"), the Commission recalls that all the legislative and regulatory provisions relating to the SNDS is applicable, in particular the ban on using this data for the purposes described in Article L. 1461-1 V of the Public Health Code. On the legality of the processing: The processing implemented by the company IQVIA is fall within the scope of its activities, which consist in particular of the supervision of clinical studies. This processing, carried out for the purposes of scientific research, is therefore necessary for the purposes of the legitimate interests pursued by the controller, with regard to the very indirectly identifying nature of the data and the guarantees, in particular in terms of the rights of individuals, provided for by the texts governing the provision of SNDS data. This processing is, as such, lawful under Articles 6, paragraph 1 point f) and 9 paragraph 2 point j) of the General Data Protection Regulation (hereinafter "GDPR"). On the purpose of the processing and their character of public interest: The processing operations requiring access to PMSI data are intended to carry out feasibility studies (hereinafter the "studies") intended to estimate the potential of French healthcare centers to host one or more clinical trials initiated, deployed and coordinated by IQVIA. 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. of public interest, in accordance with article 54 I of the law "computing and freedoms". On the categories of data processed: The Commission recalls that the data controller must only collect, for each of the processing operations implemented within the framework of this single decision, the data strictly necessary and relevant with regard to the objectives of the processing operations. provided that these files can be distributed by ATIH, in addition to the specific file allowing to link all the PMSI data concerning the same patient ("ANO" file), the data concerning the following activities are necessary for the performance of these studies: medicine , surgery, obstetrics and odontology (MCO); follow-up and rehabilitation care (SSR); collection of medical information in psychiatry (RIM-P); hospitalization at home (HAD). The treatments included in the framework of the single decision relate to national data from the

PMSI for the years 2015 to 2020. The Commission recalls that, in accordance with Article 30 of the GDPR, the controller must keep r, within the register of processing activities, the list of processing implemented in the context of this single decision. The adequacy, relevance and limited to what is necessary in relation to the purposes for which the data are processed, the geographical area concerned and the historical depth of the data consulted must be justified for each processing operation implemented within the framework of this single decision in the register of processing activities. On the data retention period: PMSI personal data cannot be stored outside the CASD platform by the data controller, their export being prohibited. Only anonymous results can be exported. The duration of access to data in the secure platform must be limited to the duration necessary for the implementation of the processing, which cannot be more than three years, from the date of effective access to data. On the publication of the results: The Commission recalls that, in accordance with Article 56 of the "Informatique et Libertés" law, when the result of the data processing is made public, the direct or indirect identification of the data subjects must be impossible. The results of the studies carried out within the framework of this single decision may be sent to IQVIA analysts as well as participating investigators. On the categories of data recipients: Only the data controller has access to the given in the context of this single decision. 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 access rights must be regularly reassessed, in accordance with the methods described in the authorization procedure established by the data controller. On information and the rights of persons: Information of the persons concerned, as to the possible reuse of their data and the procedures for exercising their rights, is ensured by a statement appearing on the website of the IQVIA company, health insurance organizations and on media allowing it to be brought to the attention of persons, in particular posters in premises open to the public or documents given to them. The rights of access, rectification and opposition are exercised with the director of the organization managing the compulsory health insurance scheme to which the person is attached, in accordance with the provisions of Article R. 1461-9 of the Public Health Code. On data security and traceability of s actions: The implementation of personal data processing occurring within the framework of the study is carried out under the responsibility of the data controller, including with third parties acting on his behalf, in compliance with the provisions of Articles 24, 25, 28, 32 to 35 of

the GDPR as well as the decree of March 22, 2017 relating to the security reference system applicable to the SNDS. The data will be made available to the data controller via the access provider designated by ATIH, namely the CASD.Only data resulting from anonymization processes, such that the direct or indirect identification of individuals is impossible, can be extracted.For relying on the anonymity of a data set, the data controller must carry out an analysis to demonstrate that its anonymization processes meet the three criteria defined by Opinion No. 05/2014 on anonymization techniques adopted by the Article 29 group (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 principle of transparency: The provision of data from the NSDS and its components is designed to account for their use to civil society. To this end, Article L. 1461-3 of the Public Health Code makes access to data from the SNDS and its components subject to the communication to the INDS of several elements by the data controller, before and after the studies. Thus, the data controller undertakes to register the studies carried out within the framework of this single decision with the public directory kept by the INDS. This registration, to be carried out by the data controller or the person acting on his behalf, before the start of the processing, is accompanied by the transmission to the INDS of a file comprising: the protocol, including the justification of the interest public, as well as a summary, according to the model made available by the INDS; the declaration of interests of the controller, in relation to the purpose of the processing. At the end of the studies, the method and the results obtained must be communicated to the INDS for publication. The recording of the treatment and the transmission of the results are carried out in accordance with the methods defined by the INDS. In addition, the Commission takes note of the commitment of the company IQVIA to transmit annually to the ATIH the list of potential cohorts studied as well as as the characteristics of the processing carried out using PMSI data. The authorization will be limited to a period of three years. At the end of this period, a report containing in particular the list of analyzes carried out within the framework of the single decision as well as the methodology followed within the framework of the analyzes must be sent to the Commission. Authorizes, with regard to the number of processing operations made necessary by its activity, the company IQVIA Operations France to implement the processing mentioned above for a period of three years, with the obligation to submit a report to the Commission at the end of this period. The PresidentMarie-Laure DENIS