DELIBERATION n°2019-100 of JULY 18, 2019National Commission for Computing and LibertiesNature of the deliberation: AuthorizationLegal status: In force Date of publication on Légifrance: Tuesday, November 05, 2019Deliberation n° 2019-100 of July 18, 2019 authorizing the company IQVIA Operations France to implement automated processing of personal data for the purpose of setting up a warehouse of personal data in oncology for the purposes of research, study or evaluation in the field of health ( Request for authorization n° 2107243 V1) The National Commission for Computing and Liberties, Seizure by the company IQVIA Opérations France of a request to modify the authorization for automated processing of personal data for the purpose of the constitution of a warehouse of personal data in oncology, for the purposes of research, study or evaluation in the field of health; on 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 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, in particular its Article L. 1461- and Given the law n ° 78-17 of January 6, 1978 modified relating to data processing, files and freedoms, in particular its section 3 relating to the processing of personal data in the field of health and its articles 44- 3° and 66 III; 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 deliberation n° 2017-347 of December 21, 2017 authorizing the company IQVIA Opérations France to implement a automated processing of personal data for the purpose of setting up a warehouse of personal data in oncology for the purposes of research, study or evaluation in the field of health; Having regard to the file and its supplements, in particular the privacy impact assessment produced on January 29, 2019; On the proposal of Mrs Valérie PEUGEOT, Commissioner, and after hearing the observations of Mrs Nacima BELKACEM, Government Commissioner, Makes the following observations: Data controllerThe company IQVIA Opérations France (hereinafter, “IQVIA”), a simplified joint-stock company with a single shareholder, resulting from the merger of the IMS Health companies, whose historical core business is the provision of regularly updated data on volumes drugs sold in pharmacies, and Quintiles, which specializes in studies and advice for the drug industries and healthcare players. the initiative to create a data network in oncology, the objective of which is to describe the uses of anticancer drugs in clinical practice in Europe, by acquiring a data warehouse dedicated to oncology and a platform called "Co-Track" dedicated to its operation. This warehouse is made up of oncology data from health establishments and services, spread over France and Europe, members of the network. It is powered by data from the information systems of

health establishments and services that have a contractual relationship with IQVIA. According to IQVIA, apart from the payment of an indemnity exclusively intended to cover the investments and expenses made by the establishment for the deployment of the device, no remuneration is paid to the establishments and health services; these have free access, in return, to the analyzes produced. in oncology. More specifically, longitudinal studies could be carried out on the therapeutic management of a patient or a group of patients in oncology, on the effective real-time use of oncology products and their prescription method, on the access to care and innovative treatments, on observance or compliance with best practices and reference treatments by practitioners who are members of the network, on comparative analyzes of the use of anti-cancer treatments within the framework of temporary authorizations for use (ATU) or after marketing authorization (MA) of products, patient analyzes (“screening”) to improve the design and recruitment of clinical trials and accelerate the identification of patients who could benefit from clinical trials, on medical management aimed at optimizing the organization of care, on medico-economic evaluations and analyses. The Commission considers that the purpose of the processing presented is determined, explicit and legitimate, in accordance with the provisions of Article 5-1-b of the GDPR.Concerning the requirement, laid down by Article 44-3° of the law, of the existence of a public interest in order to process personal health data outside of healthcare activities or with the consent of the persons concerned, the Commission notes that the satisfaction of the public interest is not reserved solely for public persons. In the present case, some of the purposes, as presented by the company IQVIA, aim to have a better knowledge of innovative anti-cancer treatments. According to the company, it is a question, by a facilitated exploitation of data collected in almost real time, of allowing, for the benefit of both private and public actors, research in the medical field (such as monitoring and carrying out epidemiological, medico-economic, compliance studies, analysis of current medical practice in oncology) or to inform the public authorities in their decision-making in terms of health policy (modifications in the consumption of an anti -cancer, pricing and access to treatments by patients, etc.). The Commission considers that the constitution of this warehouse of data from hospital information systems for the purposes of research, study or evaluation in the field of health, is in the public interest. The Commission would like to point out that the future uses of the data contained in this warehouse fall within the framework of the provisions of articles 72 and following of the law which also impose that each request for research, study or evaluation meets a requirement of public interest. Thus, the Commission considers that the use of the data contained in the processing that will be implemented by IQVIA cannot, by analogy with the prohibited purposes of use of the national health data system (SNDS), be exploited for the purposes of

promotion of health products to health professionals or health establishments or for the purpose of excluding guarantees from insurance contracts and modifying insurance contributions or premiums for an individual or a group of individuals presenting the same risk. Similarly, the Commission recalls the prohibition on compiling and using, for prospecting or commercial promotion purposes, files composed from data resulting directly or indirectly from medical prescriptions, since these files make it possible to identify directly or indirectly the prescriber (article L. 4113-7 of the public health code). In order to guarantee the character of public interest of the future uses of the data, IQVIA has decided to set up scientific and ethical committees, both at European and national level, in charge of defining a set of rules to which IQVIA will have to refer to decide the validity of research or study projects requested by the company's clients with regard to the public interest. An advisory group is created at national level, the "Country Advisory Group" (CAG) made up of qualified people, external to the company, including members of patient associations, which has the possibility of alerting the committee in place at European level, the “Clinical and Analytical Steering Committee” (CASC), when a research or study project does not seem to it to be in conformity. The validation circuit of the research, study or evaluation project is as follows: each project is examined by IQVIA with regard to the rules which will have been defined by the CASC then transmitted to the representative of the IQVIA company, sitting within the CASC. This representative, decision-maker on the project, has the possibility of seizing the CASC before deciding. In all cases, the project and the decision taken on the project by IQVIA is communicated to the CASC and to the competent CAG with the possibility for the CASC to reconsider a decision by IQVIA which does not seem to it to be in conformity. The Commission takes note of this project review mechanism put in place and that the representative of IQVIA within the CASC and the CAG has been appointed to ensure a mission of liaison between these committees and IQVIA and that he will not take not take part in their decisions.Finally, the Commission notes:that the publication of the results of research, study or evaluation projects will be examined on a case-by-case basis according to the same procedures as those described above; IQVIA's commitment to publish each year a summary of the types of analyzes produced from the data in the warehouse; IQVIA's commitment to provide the CNIL with an annual report on the operation of the data warehouse and the requests made from it. This report must in particular include a report on information and the rights of individuals. On the data processed The following data will be collected: concerning the patient of the partner establishment: a unique identifier - other than the registration number in the directory of natural persons (NIR) - allowing the same patient to be monitored within one or more establishments, composed from the patient's identifier within the establishment, the surname, first name, date of birth, postal

code of residence and sex of the person; the date of birth, the vital status and date of death if applicable, gender, local patient identifier, information about diagnosis, treatment plan, dispensing and administration of treatment, end of treatment and information about the healthcare facility (the FINESS number and address); concerning the prescriber of the partner establishment: the identification number in the shared directory of healthcare professionals (RPPS), the method and type of exercise, the speci medical unit, the identifier of the health establishment and geographical location, date and time of prescription and modification of prescription if necessary; concerning the user of the platform designated by the partner establishment: the e-mail address .The Commission notes that the date of birth will be transformed into year of birth, that the date and time of registration of prescription data will be transformed into the current date and that the patient's local identifier is subject to 'a pseudonymisation mechanism. The Commission considers that the data processed is adequate, relevant and limited with regard to the purpose pursued, in accordance with the provisions of Article 5-1-c of the GDPR. On the recipients The customers targeted by the company IQVIA are mainly partner health establishments and services, health sector manufacturers and, where applicable, public authorities. IQVIA employees will not be recipients of individual patient data from healthcare facilities or healthcare services. The studies provided by the data controller to third parties will only contain data made perfectly anonymous within the meaning of Opinion No. 05/2014 on anonymization techniques adopted by the Article 29 group (G 29) on April 10, 2014. The Board considers that the categories of recipients and the procedures for communicating the results do not call for comment. However, it draws the attention of the data controller to the obligations incumbent upon him in terms of data confidentiality and recalls that he must: respect and ensure respect for the secrecy of the information by all persons likely to work on this data; not retrocede or disclose to third parties the individual information provided in any form whatsoever; not to carry out reconciliations, interconnections, connections, pairings with any directly or indirectly nominative data file or any information likely to reveal the identity of a person and/or their state of health; not to misuse the information collected, in particular for purposes of research or identification of persons; to guarantee the confidentiality of all data transmitted to third parties, which requires the implementation of state-of-the-art encryption measures. On information and the rights of individuals The established Health organizations and health services will be responsible, contractually, for informing their patients of the processing of data concerning them, as well as allowing the exercise of the rights of access, rectification and opposition which are recognized to them. The Commission recalls that the data controller must take the necessary measures, in particular by ensuring their effectiveness, with its partners so that the persons concerned can exercise their right

of opposition directly in each establishment and health service before any transmission of data .It is expected that people will be informed individually by giving each of the patients concerned an information note and by posting a document in the reception room, waiting room or on the website of establishing the identity of the data controller, its purpose, the recipients of the information and the procedures for exercising their rights. This information will be given when the patient is admitted and prior to the implementation of the treatment. The Commission notes that the exercise of the patient's rights of access, rectification and opposition will be exercised with the healthcare professional. , the health establishment or the health service in charge of their therapeutic follow-up for non-pseudonymised data, or with the hosting doctor for pseudonymised data. In the latter case, an operational procedure is put in place to ensure the lifting of the pseudonym and the correct re-identification of the persons concerned. Health establishments and health services will also be responsible for informing prescribers of the processing of data concerning them via the platform registration document and the delivery of an information notice by the establishment in which they work. The exercise of their right of access, rectification and opposition will be made with their head of department or head of division. Finally, users are informed of the processing of their data via the online collection form when they connect to the platform and the general conditions of use of the platform. They exercise their right of access, rectification and opposition with the legal department of the company IQVIA. On the security measures The health data transmitted by the care establishments will be the subject of a pseudonymization mechanism carried out in two steps: the identification data (surnames, first names, date of birth, sex, postal code, patient identifier within the establishment) will be hashed with a secret key before being transmitted to the data controller . This secret key will be controlled and managed by the healthcare establishment or by a trusted third party. As soon as they are received by the data controller, the data will be subject to a second stage of pseudonymization aimed at degrading the data received in order to limit the risks of re-identification of persons. This sequencing guarantees that the data controller will never have access to the raw data. The pseudonymised data resulting from this mechanism will be stored in an encrypted database which will be used to carry out the studies. All of the personal health data processed is hosted by an approved host under the conditions of decree no. 2006-6 of January 4, 2006. The data controller has implemented a password policy in accordance with deliberation no. 2017-012 of January 19, 2017 adopting a recommendation relating to passwords: the persons in charge of the management, maintenance and use of data will use a strong authentication mechanism. In addition, access to databases containing personal data will be subject to detailed authorization management to determine the data and actions accessible to authorized persons. Logging of data

consultation, creation and modification operations is in place. The 6-month retention period for logs complies with the recommendations of the Commission. Data from healthcare establishments will be exchanged via encrypted communication channels and ensuring the authentication of the source and the recipient. The procedure for lifting the pseudonym requires direct and positive action by the hosting doctor, who alone is able to trigger the lifting of the pseudonym of the data. Regarding the use of the HTTPS protocol, this will be used under security conditions in accordance with the the state of the art making it possible to guarantee the confidentiality of the data transmitted. The other security measures appear to comply with the state of the art and do not call for any particular comments from the Commission; they must however be regularly updated to take into account the evolution of the risks. Finally, the Commission strongly recommends that the data controller carry out an impact study on the privacy of the persons concerned. , in order to control the risks presented by the processing for the privacy of these persons, and recalls that these impact studies must be carried out for all processing likely to present risks for the rights and freedoms of the persons concerned from the application of the general data protection regulations. On the other characteristics of the processing The data controller wishes to keep the data that has been the subject of the two-step pseudonymization process for a period of ten years in order to be able to carry out analyzes on long periods, whose usefulness is proven in terms of anti-cancer treatments. He also wishes to keep the do nnates who have undergone the first stage of the pseudonymization process for a maximum period of 3 months in order to be able to detect any malfunctioning of the pseudonymization process during the initial integration of a health establishment, then at the end of the integration of the establishment, these data will be kept for a maximum period of 30 days. The Commission considers that these data retention periods do not exceed the period necessary for the purposes for which they are collected and processed, in accordance with the provisions of the Article 5-1-e of the GDPR. Authorizes, in accordance with this deliberation, the company IQVIA Opérations France to implement the processing described above and repeals deliberation no. 2017-347 of December 21, 2017. The Commission recalls that the processing of personal data which will be implemented subsequently for the purposes of research, study or evaluation in the field of health is processing of istincts which must be the subject, by the company IQVIA Opérations France, of specific formalities provided for in articles 72 and following of the law n ° 78-17 of January 6, 1978 modified. The President Marie-Laure DENIS