Deliberation 2021-015 of February 4, 2021Commission Nationale de l'Informatique et des LibertésNature of the deliberation: AuthorizationLegal status: In force Date of publication on Légifrance: Tuesday August 24, 2021Deliberation n° 2021-015 of February 4, 2021 authorizing the company IQVIA OPERATIONS FRANCE to implement automated processing of personal data for the purpose of a health data warehouse, called EMR (Authorization request no. 2212249) The National Commission for Computing and Liberties, Entry by IQVIA Operations France a request for authorization concerning the automated processing of personal data for the purpose of a health data warehouse; Having regard to Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 relating to the protection of persons with regard to the processing of personal data and the free movement of such data, and repealing Directive 95/46/EC (GDPR); Considering the modified law n° 78-17 of January 6, 1978 relating to data processing, files and freedoms, in particular its articles 44-3° and 66-III; On the proposal of Mrs Valérie PEUGEOT, commissioner, and after having heard the observations of Mr. Benjamin TOUZANNE, Government Commissioner, Makes the following observations: Responsible for processing The company IQVIA Opérations France, a simplified joint-stock company with a single shareholder. On the purpose The company IQVIA Opérations France wishes to implement an EMR data warehouse (electronic medical records) to conduct studies on the evaluation and analysis of care practices in general medicine. This database will be fed by personal data gathered in two pre-existing databases comprising longitudinal data extracted from software from general practitioners in France: the disease analyzer (DA) database includes data from software from doctors who have signed co ntrats with IQVIA Opérations France as part of its Medical 21 network; the longitudinal patient data base (LPD) formerly known as the THALES observatory includes data collected by the company Cegedim Health Data in a database called THIN and transmitted to IQVIA Opérations France in the framework of a contract for the provision of services. The purpose of the processing envisaged is to constitute a warehouse of personal data including in particular health data. The latter aims to allow the performance, in the field of research, of activities following: estimation of the prevalence of diseases; analysis of patient care according to their pathologies; analysis of the socio-demographic and medical characteristics of patients according to pathologies; evaluation of the correct use of drugs; analysis of demographic disparities , regional and physician care profiles; follow-up of patient cohorts and monitoring of the occurrence of secondary events, if any undesirable; measurement of healthcare consumption; evaluation of the care pathway in the city in its entirety, and its economic valuation. The Committee considers that the purpose of the treatment is determined, explicit and legitimate, in accordance with the provisions of Article 5-1-b of the GDPR. The Commission considers that the

provisions of Article 44-3° and 66-III of the law of 6° January 1978 as amended, which submit to its authorization processing involving data relating to health and justified, as in this case, by the public interest. The legal basis for the processing is the legitimate interest, within the meaning of Article 6-1-f of the GDPR, of the data controller, for the purposes of scientific research, pursuant to Article 9-2-j of the GDPR. will fall under the provisions of the Articles 66 and 72 and following of the Data Protection Act, which require that each research, study or evaluation project be justified by the public interest and must be subject to specific formalities. Thus, the Commission considers that the data contained in the processing that will be implemented by the company IQVIA Opérations France cannot, by analogy with the prohibited purposes of use of the national health data system (SNDS), be used for purposes of promoting health products to health professionals or health establishments, or for the purpose of excluding guarantees from insurance contracts and modifying contributions or insurance 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). The Commission notes that the data controller has put in place a governance mechanism for the EMR warehouse in order to control the use that will be made of it in full compliance with the declared purposes and the public interest. It is made up of two committees: the operational committee for data governance ensures the proper use of data from the EMR warehouse, controls study projects and can refer to the Strategic Committee to which it sends a regular report of requests that it examines the Data Governance Strategic Committee, approves the data governance policy proposed by the Operational Committee and defines IQVIA Operations France's strategy in this area. The Commission notes that a validation process for the analyzes allows, under certain conditions, referral to the Operations Committee and then to the Strategy Committee. The Commission requests that referral to the operational committee be systematic. The Commission also notes that IQVIA Opérations France has a policy for the prevention of conflicts of interest and corruption, which applies to the members of the aforementioned committees. Furthermore, the Commission takes note of: IQVIA Opérations France's commitment to publish each year a summary of the types of analyzes produced from the data of the warehouse in the annual report sent to the Commission as well as on the website of 'IQVIA Opérations France mentioned in the information note intended for the persons concerned; the commitment of IQVIA Opérations France to communicate to the Commission an annual report on the operation of the data warehouse and on the studies and research projects carried out since then. The

Commission suggests, for the sake of transparency, the publication of a summary and the results of each research, study or evaluation project carried out on the data. of the warehouse on the IQVIA Opérations France website mentioned in the information notice for data subjects. The Commission points out that the transparency requirements provided for in Article L. 1461-3 of the Public will be added in the event that data from the EMR warehouse is matched with that of the national health data system. On the data processed Data relating to patients: identification data: random patient code specific to each medical practice, year of birth, gender, marital status, number of children, socio-professional category; health data from the medical consultation carried out by the doctor: date of visit, events, diagnoses, symptoms, allergies, risk factors, weight, height , BMI, blood pressure, pulse, disease severity scales and score, drug prescriptions (date, molecule, drug name, ATC class, dosage, duration of prescription, posology, name number of boxes prescribed,prescription of vaccines,prescriptions for additional examinations (biological and radiological),results of biological analyses,referral to specialists,prescription of paramedical care,dates of sick leave,medical ALD.Data relating to professionals of health and to users: identification data: doctor code, year of birth, sex, department; professional life: year of thesis, doctor's specialty, sector 1 or 2, particular mode of practice. 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. On the recipients The pseudonymised data contained in the warehouse may be transmitted for research, study and evaluation purposes: to the authorized personnel of the company IQVIA Opérations France; to the authorized personnel of certain subsidiaries of IQVIA Op erations France.These recipients will have access to the data within the limits of those strictly necessary and relevant with regard to their functions and missions. The Commission points out that this access must be carried out with strict respect for the confidentiality of the data. within the framework of subsequent research, study or evaluation projects; to the European Medicines Agency (EMA) within the framework of a partnership contract. These data sets will thus have been the subject of a assessment of the risk of re-identification using a modeling of the threat with regard to their nature and the security context in which they will be used, then a de-identification adapted to the precise context of their distribution, according to a methodology that has been the subject of several publications and operated by dedicated software. The risk assessment will be reviewed every 18 months. In addition, the Commission notes that no data in the EMR warehouse will be accessible to business partners of IQVIA Opérations France. In this regard, the Commission recalls that pseudonymisation , even reinforced, only constitutes a security measure aimed at reducing the risks for the persons concerned and in no way exonerates the various

actors from their obligations related to the protection of personal data.Any communication of data to other categories of recipients must be the subject of formalities with the Commission in order to modify this authorisation. On information and the right of access The Commission points out that the persons concerned must be individually informed of the processing and that the various data media information must include all the information provided for by the provisions of the GDPR. ns feeding the disease analyzer data flow are informed via dedicated contractual clauses in the contract established with the company IQVIA Opérations France. The rights of access, rectification and opposition of health professionals are exercised by email to the company IQVIA Opérations France, to a dedicated e-mail address. With regard to healthcare professionals supplying the LPD flow: The Commission recalls that it is up to IQVIA Opérations France, in its capacity as data controller, to send Cegedim Health Data a information note intended for healthcare professionals in accordance with the provisions of the GDPR and to ensure that this information will be given to them. IQVIA Operations France must also provide for the procedures for exercising the rights of these healthcare professionals. patients whose data comes from the DA flow: IQVIA Opérations France will give each partner doctor supplying the DA data flow printed information leaflets to be communicated to each patient. This information comes in addition to the general information that will be displayed by the doctors on their premises, also provided by IQVIA Operations France and which will highlight the possibility for the persons concerned to exercise their right of opposition. A QR code as well that a link to a website allowing each patient to access, before the consultation, an information note on their mobile phone will be displayed on these posters. The CNIL notes that the information note intended for patients of physicians of the DA network refers to a website on which the information notes of each study carried out on the basis of the data of this repository will be published before their implementation. The link mentioned in the information sheet must refer to the page on which the studies reusing data from the warehouse are mentioned and not to a home page. The CNIL requests that this site be updated before each start of 'study. At the end of each study, IQVIA Operations France must publish a summary of the study as well as links to the publications related to the study. The Commission notes that the rights of access, rectification and opposition of the patient will practice with the doctor using the professional software and participating in the care of the person concerned or the doctor hosting the company IQVIA Opérations France. In this respect, it notes that the doctor can materialize the opposition of the patient to the processing of its data in the warehouse by means of a tick box. The Commission therefore recalls that a secure operational procedure must be put in place in order to ensure the lifting of the pseudonym and the correct re-identification of the persons concerned in respect for the confidentiality of the data processed.

To this end, it recalls that measures similar to those provided for the exercise of rights in the context of IQVIA Oncology treatment (deliberation no. 2017-347 of December 21, 2017) could be put in place. the data comes from the LPD flow: The Commission notes that IQVIA Opérations France, having no direct contact with the professionals transmitting data within the framework of the LPD flow, sent Cegedim Health Data an information note to destination of patients. It is Cegedim Health Data's responsibility to transmit information to healthcare professionals in order to guarantee that patients are correctly informed prior to the processing of data concerning them, in accordance with Article 14 of the GDPR. Regarding the reuse of data for research purposes The Commission recalls that the information relating to the constitution of the warehouse cannot replace the prior individual information provided for by the provisions of the GDPR and the Data Protection Act, which must be carried out for each processing of data produced from data from the warehouse. On security measures Data collection is carried out with partner doctors of the company IQVIA Opérations France (about 5000) from their patient management software, via the editors of this software, according to two scenarios: the software installed at the partner doctor transmits the data, with a pseudonym identifier ized and on an encrypted communication channel, to a flow concentrator operated by the software publisher; the doctor's software is offered as a cloud service, in which case the data is already hosted by the publisher. The Commission notes that the pseudonymized patient identifiers will be specific to each medical practice, without chaining a patient between several practices, and that the data collected will be generalized to the month and year of birth of the patient. Then, after encryption, the data will be transmitted by the various publishers to the EMR Hub of the company IQVIA Opérations France (concentrator of data from the various sources), on a communication channel itself encrypted with a specific certificate. The encryption keys will be renewed regularly and protected by password. The Commission reminds the data controller that it is responsible for ensuring, by contractual means and technical audits, that all publishers – as processors under the GDPR – comply with the procedures it has defined for secure end-to-end data transmission, from storage at the doctor's workstation to deposit on the EMR Hub. The EMR Hub will reside in an encrypted database at an approved or certified host for the hosting of health data (HDS) falling exclusively within the jurisdictions of the European Union. These data will be hosted in France and will be subject to reinforced pseudonymization upon receipt, with generation of new patient and doctor identifiers, generalization to the year of birth, deletion of the place of visit and desensitization of free text areas. Finally , the data will be encrypted and transmitted by the EMR Hub over an encrypted communication channel to the EMR warehouse hosted on the premises of IQVIA Operations France. Data specific to doctors will also be entered into the GISM database of

the company IQVIA Opérations France for the management of panels and the management of commercial relations with partner doctors, which constitutes a separate processing operation from the EMR warehouse. will be partitioned: access to data from the EMR warehouse takes place in a specific area of the IQVIA Operations France network, physician panel managers will not have access to patient data, and analysts and clinical research associates authorized and authorized persons who will have access to patient data will not have access to the doctor's original identifier. IQVIA Opérations France will also implement general security measures: the various directories for the transit and temporary processing of data, including those on the EMR Hub, will be purged immediately after each operation; all internal data transfers will take place over a totally private network; backups will be stored in network areas with restricted access; remote access and other transfers will be done by virtual private network (VPN) – with a ban on the use of mobile storage media – and all data transfers will be traced; moreover, the premises hosting the EMR warehouse are protected by access control by individual badge and monitoring and alarm equipment. The Commission notes that, to remedy a technical failure of the EMR warehouse, the data sent by the EMR Hub to the warehouse will be kept on the Hub with the same duration as those of the warehouse, in order to be able to restart the import processing. In this regard, it recommends protecting this data with the same level of security as that of the warehouse. All administrator and user accounts who will be duly authorized to access the non-aggregated data of the EMR Hub and the EMR warehouse will be subject to strong authentication (username and password coupled with a token generating a one-time password). All access accounts will be nominative and authorizations will be subject to the approval of the appropriate committee according to the level requested, of the Human Resources department and of the authorizations manager. In addition, access to warehouse data by third parties (for example, scientific partners) will only be done from the premises and equipment of IQVIA Operations France, with accounts specifically created for this access. The Commission recommends concluding with all collaborators and third parties accessing patient data from the warehouse a confidentiality agreement or any other type of equivalent contractual stipulations. Clearances will be reviewed and updated every six months for permanent clearance profiles and monthly for temporary authorization profiles. In addition, an account deactivation procedure will be put in place in order to manage authorization changes during the year and the possible departure of employees authorized to access the data. Aggregated statistical data on a minimum of 10 patients will also be produced. Access to the warehouse will be traced and the traces will be kept read-only for a period of six months and then will be deleted. Exports will be logged and monitored to identify cases of abnormal use or export of data from the servers of the

company IQVIA Opérations France. In this respect, the Commission recommends implementing an automatic analysis of exported data. The Commission notes the deployment of a system making it possible to trace all actions on the warehouse, to 'export all the traces to a secure collector and analyze them automatically in order to generate a dashboard and alerts for the team operating ipe of the platform and the data governance committee. The latter will decide on appropriate action plans, monitor them over time, and keep the data protection officer informed of any breaches and their resolution. A specific procedure has also already been communicated to the staff of IQVIA Opérations France to deal with data breaches by directly involving the latter's data protection officer. On data transfers The Commission notes that the implementation of this warehouse does not result in the transfer of personal data, directly or indirectly identifying, outside the European Union. On the other characteristics of the processing The data will be kept in an active database for a period of ten years. Beyond that, the data will be anonymized or deleted. In this respect, the Commission notes that this operation will be automated. The Commission considers that this data retention period does not exceed the period 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 IQVIA OPERATIONS FRANCE to implement the aforementioned processing. President Marie-Laure DENIS