

## HEALTH DATA: RELEASE TO INFORM

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Debate led by **Vincent OLIVIER**, President of Recto Verso | France

### **Data access conditioned by an undefined ‘public interest’**

Releasing healthcare data entails risks related to national sovereignty. In this respect, its access is regulated. Any individual or organization, whether public or private, may access data of the French National Health Data System (SNDS) with authorization from the French data protection authority (CNIL) to carry out data processing in the public interest. The CNIL may request the opinion of the Ethics & Scientific Committee for Health Research, Studies & Evaluations (CESREES) to decide on the public interest of a research project. In case of a negative opinion, the applicant can appeal to the French Council of State for a final decision. The difficulty lies in the fact that neither law nor jurisprudence from the Council of State or the Constitutional Council defines what ‘public interest in health’ means. The definition of such a crucial issue should not be left to a public interest group like the Health Data Hub, or an independent administrative authority such as the CNIL. It is therefore necessary for the law to take a position on this definition. The use of personal healthcare data for purposes of public interest would mean improving knowledge of health and the overall healthcare system. Moreover, pursuing public interest does not mean excluding the private sector, although cautiousness is required, as this data is particularly personal and sensitive.

### **The importance of health data in population-based responsibility**

Population-based responsibility, as experimented in certain areas under Article 51, entails that all healthcare stakeholders share responsibility for meeting expressed and unexpressed healthcare needs in a given area. To identify healthcare needs, it is essential to leverage national databases and create clinical and health-economic stratifications of populations. These stratifications help categorize patients, providing a detailed summary of healthcare needs, to adapt care pathways, healthcare programs, and to evaluate the implemented measures. This stratification, which can be easily applied by healthcare professionals, helps reducing the reliance on emergency service and long-term hospital stays, ensuring better population monitoring. Several countries and regions (the Netherlands, Catalonia, Italian regions, Belgium, Switzerland, United Kingdom) also operate on a territorial basis.

### **The timeframe for accessing health data is a hindrance to research competitiveness.**

The CESREES has one month to give its opinion to the CNIL, which then has two renewable months. Some organizations may have direct access to data without going through the CNIL and CESREES, provided they can directly inform patients. The issue lies in the provision of data after authorization. The Health Data Hub, a national platform for health data and a single gateway to facilitate access to requests, was initially intended to play this major role in making data available. However, for sovereignty reasons, the French National Health Insurance Fund (CNAM) has taken over this role. If the CNAM encounter difficulties resulting in delays in data provision, it is because it is not its primary role. Faced with these challenges, prioritizing requests in terms of relevance becomes necessary. Delays impede competitiveness, whereas in Spain and the United Kingdom, data can be accessed and regularly updated in 1 to 3 months. The UK is also working on simplifying the General Data Protection Regulation (GDPR) system. No country has a national healthcare database of the quality seen in France. Yet it is still poorly exploited. The challenge for industry is to remain competitive compared to other countries. If manufacturers can access this data in any country, they might as well do it in France. Shared ambition is what can make France an area of research into high-quality healthcare data.

### **The need to educate about the reluctance of health data holders**

In France, people have a “proprietary instinct” towards their data and mistrust industries in the use they make of it. However, since it is health insurance data and data platforms are publicly funded, it could be argued that this data belongs to everyone. Patients need to be educated on the matter. On the one hand, it is important to explain that manufacturers do not own the data, that it is anonymized and processed by a third party. On the other hand, it is necessary to explain that the benefits of freeing up data are first and foremost beneficial to the patient. For instance, it enables the use of a treatment to be extended to a certain population. In fact, laboratories may lack information on certain populations, such as pregnant women. Access to cohorts of data, supplemented by certain pharmacological studies, enables the French National Agency for Medicines and Health Products Safety (ANSM) to obtain an extension of the marketing authorization for the use of a treatment for the population in question. At the same time, data holders sometimes make inappropriate use of their own data on social networks. In this respect, citizens need to be made more responsible.

### **The need for access to health data to evaluate public policy**

Health data is essential and political in that it enables those who vote on and implement health policies to evaluate them. Although the French Directorate for Research, Studies, Assessment and Statistics (DREES), the Court of Auditors and the Mission for the Evaluation and Control of Social Security Funding Laws (MECSS) provide relevant reports and data, the fact remains that they are often obsolete and do not allow health policies to be adapted.