

## **Collective information note on the protection of personal data in the context of studies requiring access to data from the National Health Data System (SNDS)**

In accordance with the provisions of article 14 of the GDPR, this collective information notice describes the measures implemented in the context of studies which do not allow individual information and which require access to data from the National Health Data System (SNDS).

This data will not be transferred outside the European Union.

The study implemented by Wockhardt UK Limited, member of the **Valproate Consortium**, as part of this system for accessing data from the SNDS, is referenced below:

- **Study:** Drug Utilisation Study extension of valproate and related substances, in Europe, using databases.
- **Data processor:** The study is carried out by IQVIA France, which has made a compliance undertaking to the CNIL.
- **Legal basis:** In accordance with article 6 of the GDPR and article 5 of the law Informatique et Libertés, the processing carried out as part of this study is based on the legitimate interests of Wockhardt UK Limited in its capacity as a healthcare industrial company, pursuing an objective of research, studies, evaluation, and innovation in healthcare.  
In accordance with article 9 of the GDPR, the processing of this personal data concerning health is for scientific research purposes; on July 20<sup>th</sup> 2023, the Comité Ethique et Scientifique pour les Recherches, les Etudes, et les Évaluations en Santé (CESREES) indicated that the study was in the public interest.  
This study has been authorised by the Commission Nationale de l'Informatique et des Libertés (CNIL) in accordance with article 66 of law no. 78-17 of 6 January 1978, as amended (decision DR-2023-174).
- **Purpose:** The main objective of this study is to assess the impact of the implementation of the risk minimization measures (RMM) and pregnancy prevention program (PPP) on the real-world use of valproate and related substances in women of childbearing potential (WCBP) in Europe.
- **SNDS data used:** Data extracted from the Datamart de Consommation de soins Inter-Régime (DCIR) database and the Programme de Médicalisation des Systèmes d'Information (PMSI) database between 2008 and 2022.
- **Data retention period:** 6 years after availability (scheduled for 2027).
- **Data Controller:** Wockhardt UK Limited, joint data Controller with the other members of the Valproate consortium.
- **Data Protection Officer (major member):**  
Can be reached at [human.resources@wockhardt.co.uk](mailto:human.resources@wockhardt.co.uk)

In order to exercise their rights of access and rectification of data, as well as their rights to object to and limit the processing of such data, the persons concerned by the processing shall send their request, providing proof of their identity by any means, to the director of the Health Data Platform or to the director of the compulsory health insurance body to which they belong.

Data subjects also have the right to lodge a complaint with the Commission Nationale de l'Informatique et des Libertés (CNIL), 3 Place de Fontenoy, 75007 Paris.