Corporate Headquarters
Consilient Health Limited
Block 2A Richview Office Park
Clonskeagh
Dublin
D14 Y0A5
Ireland
Tel: (01) 2057760

05 12 2024

Information Note specific to the AVALON project

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

Title of research	Characterization of neurodevelopmental disorders in children exposed in utero to valproate and/or other antiepileptic drugs with long-term follow-up: retrospective study on SNDS. This study is called: AVALON.
Data controller	**Lab name: Consilient Health Ltd** Address: Block 2A Richview Office Park, Clonskeagh, Dublin 14, D14 Y0A5 Society registration number 347231
Contact details of the data controller's Data Protection Officer (DPO)	**DPO name: John Fagan** E-mail: jfagan@consilienthealth.com Phone: Tel: (01) 2057760 Address : Block 2A Richview Office Park, Clonskeagh, Dublin 14, D14 Y0A5 Society registration number 347231
Data processor (in charge of handling and analysis of data)	**IQVIA Operations France (IQVIA)** Address : 17 bis Place des Reflets 92400 Courbevoie, France Society registered with the Nanterre Trade and Companies Register under number 347 939 415
Study objectives	The main purpose of the processing of personal data by Consilient Health is to assess the long-term (10 years) risks of neurodevelopmental disorders (such as autism spectrum disorder, attention deficit disorder with or without hyperactivity, communicative impairments, intellectual impairments, disorders of psychological development, movement disorders) and minor congenital malformations in newborns and children exposed to valproate and other anti-epileptic drugs during pregnancy.
Regulatory basis	In accordance with Article 6 of Regulation 2016/679 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (GPRD) and Article 5 of the French Data Protection Act (Loi Informatique et Libertés), the processing carried out in the context of this study is based on the legitimate interest of the Consilient Health in its capacity as a healthcare industrialist, pursuing an objective of research, studies, evaluation and innovation in healthcare. In accordance with Article 9 of the RGPD, the processing of personal data concerning health meets scientific research purposes; on December 14, 2023, the Comité Ethique et Scientifique pour les Recherches, les Etudes, et les Évaluations en Santé (CESREES) signified that the study was of public interest.

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	This study has been authorized 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-2024-004 du 05 January 2024)
Public interest of study	The public interest is justified by the importance of better understanding the long-term effects of prenatal valproate exposure on the risk of neurodevelopmental disorders in children. The study will make it possible to assess the risk according to existing neurodevelopmental subtypes and trimesters of pregnancy of exposure, and to characterize the evolution of disorders over a period extending from birth to 10 years of age. These elements are essential to ensure health monitoring and to inform the regulatory authorities, the scientific community and the general public about the risks associated with valproate, as well as to improve the management of pregnant women and women of childbearing age.
Categories of concerned people	The study population is composed of infants born in France between 01/01/2011 and 31/12/2013 from mothers from all health insurance scheme who have been exposed to valproate or other antiepileptic drugs in the year before birth.
Data categories	This study employs data from the French National Health System Database, SNDS (Système National des Données de Santé) which is managed by the health insurance which collects data on all healthcare reimbursed in France, whether in the home or in hospital. The data processed in the SNDS includes data relating to hospitalizations (illness responsible for hospitalization and associated co-morbidities) and/or data relating to care provided in the community and reimbursed by the health insurance scheme (medical consultation, delivery of treatments, medical procedures, chronic diseases exempted), as well as socio-demographic data (age/year of birth, sex, etc.). For more information on the components of the SNDS, please visit the SNDS website at the following link: https://www.snds.gouv.fr/SNDS/Composantes-du-SNDS. Some of the data collected in this way will be used to **carry out statistical analyses** for the AVALON study, for which Consilient Health is responsible.
Data access and recipients	Consilient Health does not access your personal data from the SNDS. Only duly authorized IQVIA personnel (data managers / statisticians / data scientists / epidemiologists) have access to it. IQVIA will send Consilient Health a study report in the form of tables/figures containing aggregated data. Access to the data will be via a secure solution provided by IQVIA Operations France (17 bis Place des Reflets 92400 Courbevoie, registered with the Nanterre Trade and Companies Register under number 347 939 415), a consultancy commissioned by Consilient Health which is responsible for implementing data processing for this project.

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	Access is limited to the needs and duration of the study. No personal data is extracted from the secure server.
Duration of data storage	In accordance with the authorization granted by the CNIL for this study, the data will be accessible for a period of 5 years from the time they are made available to IQVIA, corresponding to the time required to implement the processing. The data will then be subject to a secure archiving procedure for a period of 3 years after publication of the study results.
Data transfer outside the European Union	No transfer outside the European Union
Private life	In accordance with the requirements of the French Public Health Code, the personal data contained in the database used for this study cannot be used to directly identify the individuals to whom they relate.
Exercise of rights and claims	In accordance with the GPRD and the Loi Informatique et Libertés, you have, as a matter of principle, the right to access, rectify, limit and object to your data. In accordance with the Public Health Code, to exercise your rights and if you wish to object to the processing of your data necessary for the needs of this project, you should address yourself, providing proof of your identity by any means, directly to the director of the Health Data Platform (Health Data Hub, https ://www.health-data-hub.fr/contact) or to the director of the compulsory health insurance managing body to which you belong. Consortium Valproate does not have your identity for the purposes of this research and will not be able to identify you to enable you to exercise your rights. We remind you that for general opposition to any re-use of SNDS data, the provisions of article R 1461-9 of the CSP relating to the procedures for exercising rights stipulate that rights of access, rectification and opposition may be exercised by contacting the Direction de la Plateforme des Données de Santé (Health Data Hub, https ://www.health-data-hub.fr/contact) or the director of the compulsory health insurance organization to which you are attached. Finally, you have the right to lodge a complaint with the Commission Nationale de l'Informatique et des Libertés (CNIL) online or by post at 3 Place de Fontenoy - TSA 80715 - 75334 PARIS CEDEX 07.

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Appendix

List of DPO contacts of societies members of Valproate Consortium (Data Owner):

- ARISTO PHARMA GMBH: dsb@fox-on.com or by postal address: fox-on Datenschutz GmbH, Pollerhofstr. 33a, 51789 Lindlar, Allemagne
- ARROW GENERIQUES (société faisant partie du groupe AUROBINDO) : dpo@laboratoire-arrow.com/ dpo@aurobindo.com or by postal address : 26, avenue Tony Garnier, 69007 Lyon, France
- BETAPHARM ARZNEIMITTEL GMBH : info@dataguard.de or by postal address : DataCo GmbH Dachauer Straße 65 80335 München, Allemagne
- CONSILIENT HEALTH LIMITED: jfagan@consilienthealth.com or by postal address : Consilient Health Ireland address - Floor 3, Block 3, Miesian Plaza, Dublin 2, D02 Y754, Ireland
- CRESCENT PHARMA LTD : dave.agrella@orcimedlifesciences.com or by postal address : C8, Naxxar Gardens, Konti Manduca Street, Naxxar (MALTE)
- DESITIN ARZNEIMITTEL GMBH: datenschutz@desitin.de. or by postal address : DESITIN ARZNEIMITTEL GMBH, Weg beim Jaeger 214, 22335 Hamburg, Allemagne
- GENERIS FARMACÊUTICA S.A. (société faisant partie du groupe AUROBINDO) : dpo@aurobindo.com / delia.goncalves@generis.pt or by postal address : Rua João de Deus, 19, 2700-487 Amadora, Portugal
- G.L. PHARMA GMBH : dataprivacy@gl-pharma.at or by postal address : G.L. Pharma GmbH, Leopold-Bartenstein-Straße 1A-8502 Lannach, Autriche
- SANDOZ/HEXAL AG : sandoz_global.dpo@sandoz.com or by postal address : Industriestrasse 25, 83607 Holzkirchen, Allemagne
- LUPIN HEALTHCARE (UK) LTD: dpo@lupin.com or by postal address : Urban building, 3-9 Albert Street, SL1 2BE, Slough, Royaume-Uni
- NEURAXPHARM ARZNEIMITTEL GMBH : gdpr@neuraxpharm.com or by postal address : Elisabeth-Selbert-Str. 23, 40764 Langenfeld, Allemagne
- ORION CORPORATION : privacy@orion.fi or by postal address : Orion Corporation, P.O. Box 65 (Orionintie 1A), FI–02101 ESPOO, Finlande
- SANOFI-AVENTIS : privacy-office-france1@sanofi.commailto:privacy-office-global@sanofi.com or by postal address : SANOFI WINTROP INDUSTRIE, 82 avenue Raspail 94255 Gentilly, France
- STADA ARZNEIMITTEL AG : compliance@stada.com or by postal address : Data Protection Officer, STADA Arzneimittel AG, Stadastraße 2-18, 61118 Bad Vilbel, Allemagne
- TECNIFAR S.A.: dpo@tecnifar.pt or by postal address : TECNIFAR - INDÚSTRIA TÉCNICA FARMACÊUTICA, S.A., R. José da Costa Pedreira 11B, 1750-130 Lisboa, Portugal
- TEVA PHARMACEUTICALS EUROPE B.V. : EUprivacy@tevaeu.com or by postal address : Teva Santé, Cœur Défense, 100-110, Esplanade du Général de Gaulle, F 92931 La Défense Cedex, France
- VIATRIS HEALTHCARE SAS (FORMERLY MYLAN EMEA SAS) : dataprivacy@viatris.com or by postal address : Viatris France, 1 bis place de la Défense, Tour trinitry, 92400 Courbevoie, France
- WOCKHARDT UK LIMITED: hullas.gupta@wockhardt.co.uk or by postal address : Ash Road North, Wrexham Industrial Estate, Wrexham, LL13 9UF, Royaume-Uni

Contact DPO de IQVIA (responsable de la mise en œuvre du traitement) :

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Consilient Health Limited
Block 2A Richview Office Park
Clonskeagh
Dublin
D14 Y0A5
Ireland
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- IQVIA Operations France SAS : barbara.bressolles@iqvia.com or by postal address : IQVIA opérations France SAS, 17 bis place des reflets, 92060 La Défense, France