

18 March 2023
EMA/51069/2023

Data Analysis and Real World Interrogation Network (DARWIN EU®) Record of Processing Activities

Name and reference number of processing operation: EMA-TDA-007-RoPA-DARWIN EU

1.	Last update of this record, version number:	16/12/2023, v0.1
2.	Reference number:	EMA-TDA-007-RoPA-DARWIN EU
3.	Name and contact details of controller:	Head of the Data Analytics and Methods Task Force is appointed as 'Internal Controller'
4.	Name and contact details of DPO:	datacontroller.analytics@ema.europa.eu
5.	Name and contact details of joint controller (where applicable)	Not Applicable
6.	Name and contact details of processor (where applicable)	The DARWIN EU® Coordination Centre represented by Erasmus MC acts as the data processor. The contact details of the data processor are the following: dataprotection@darwin-eu.org
7.	Purpose of the processing	The Data Analysis and Real-World Interrogation Network (DARWIN EU®) establishes a network of data, expertise, and services, that supports better decision-making throughout the medicinal product lifecycle with reliable evidence from real world healthcare data. EMA, has established the DARWIN EU® CC to provide timely and reliable evidence on the use, safety and effectiveness of medicines for human use, including vaccines, from real world healthcare databases across the European Union (EU).
8.	Description of categories of persons whose data EMA processes and list of data categories	Business contact information directly collected from data subjects for the purpose: <ul style="list-style-type: none"> • obtain access to specific tooling, e.g., Cloud Services to upload study results. • setup a contract with the CC as Data Partner.

		<p>This may include the following: name of the person, organisation, title, email address, phone number, details of the involved organisations such as bank account details, address details, contact persons.</p> <p>No personal data will be processed by or shared with the DARWIN EU® CC and the EMA from patients or healthcare professionals that are included in the data sources that participate in the DARWIN EU® Data Network for the conduct of non-interventional scientific studies.</p> <p>No personal data is shared by the DARWIN EU® data partners with the DARWIN EU® CC since data will only be provided in aggregated and therefore anonymised format.</p>
9.	Time limit for keeping the data	<p>Personal data are maintained for a period of five years (starting from the payment of the balance of the DARWIN EU® framework contract).</p> <p>The anonymous aggregated study results will be kept as long as necessary in compliance with the pharmaceutical legislation¹.</p> <p>No additional anonymisation is necessary, but the study results as a whole will be archived in an encrypted format.</p>
10.	Recipients of the data	The DARWIN EU® Coordination Centre management team and administrators of tools used for study and data network operations.
11.	Are there any transfers of personal data to third countries or international organisations? If so, to which ones and with which safeguards?	No personal account data is transferred to third countries or international organisations. All servers that host tools developed or used by the DARWIN EU® CC are located in the European Economic Area.
12.	General description of security measures, where possible.	Two-factor authentication, role-based access, and IP whitelisting is applied where possible. Data is encrypted in rest and in transit.
13.	For more information, including how to exercise your rights to access, rectification, object and data portability (where applicable), see the privacy statement:	https://darwin-eu.org/index.php/privacy-statement

¹ [EudraLex - Volume 1 \(europa.eu\)](https://eur-lex.europa.eu/)