***** This document is for information only *****

You will need to apply online in order to add a Study

'Add a Study' Questionnaire

RWD Catalogues

Please complete the questionnaire to register your study in the RWD Catalogues. Mandatory fields are marked with an asterisk (*).

The questionnaire comprises **23 questions** divided in **3 steps**: Administrative Details, Methodological Aspects and Data Management. You agreed with the terms and conditions when you joined the RWD Catalogues.

Step 1: Administrative details

1. Study identification

DARWIN EU® study: *Study performed by DARWIN EU®* [Toggle switch]

- □ Yes
- □ No

Official title and acronym* [Free text] *Acronym to be added in parentheses after the study title*

Study countries* [Drop-down menu, includes European Union option] *Countries in which this study is being conducted*

Study description [Free text, limited by 2000 characters]

2. Research institution and networks

Institution conducting the study [Drop-down menu with Institutions registered in RWD Catalogues] *Name of lead institution conducting the study.*

Institution conducting the study if not in the list [Free text] *Enter the name of institution if not in the catalogue yet. If an institution is not included in the catalogue, please consider adding it here: Add institution in the catalogue. Note that a few days may be needed for the approval of the new institution in the catalogue. Once the institution is approved, you will be able to link it to a study and other content of the catalogue.*

Additional institutions [Drop-down menu with Institutions registered in RWD Catalogues]

Additional institutions if not in the list [Free text] *Enter the name of institution if not in the catalogue yet. If an institution is not included in the catalogue, please consider adding it here: Add institution in the catalogue. Note that a few days may be needed for the approval of the new institution in the catalogue. Once the institution is approved, you will be able to link it to a study and other content of the catalogue.*

Network conducting the study [Drop-down menu with Networks registered in RWD Catalogues] *Name of the networks associated with the study*

Additional networks if not in the list [Free text] *Enter the name of network if not in the catalogue yet. If a network is not included in the catalogue, please consider adding it here: Add network in the catalogue. Note that a few days may be needed for the approval of the new network in the catalogue. Once the network is approved, you will be able to link it to a study and other content of the catalogue.*

3. Contact details

Name and e-mail address provided here will be made public. A functional (organisation) contact e-mail may be provided

Study institution contact*

First name* [Free text]

Last name* [Free text]

Email* [Free text]

Primary lead investigator*

First name* [Free text]

Last name* [Free text]

ORCID number [Free text]

4. Study timelines

	Planned	Actual
Date when funding contract was signed*	[dd/mm/aaaa] __/__/____	[dd/mm/aaaa] __/__/____
Study start date*	[dd/mm/aaaa] __/__/____	[dd/mm/aaaa] __/__/____
Data analysis start date	[dd/mm/aaaa] __/__/____	[dd/mm/aaaa] __/__/____
Date of interim report, if expected	[dd/mm/aaaa] __/__/____	[dd/mm/aaaa] __/__/____
Date of final study report*	[dd/mm/aaaa] __/__/____	[dd/mm/aaaa] __/__/____

5. Source of funding

Source of funding [Drop-down menu]

- □ EMA
- □ EU institutional research programme
- □ National competent authority (NCAs)
- □ No external funding
- □ Non for-profit organisations (e.g.,charity)
- □ Non-EU institutional research programme
- □ Other public funding (e.g., hospital or university)
- □ Pharmaceutical company and other private sector
- □ Other

More details on source of funding [Free text] *If the source of funding is a pharmaceutical company, the company name should be added in this field. In case more than one companies have funded this study, the names should be separated by commas. If the source of funding does not match the categories available, further information should be provided in this field.*

6. Study protocol

Please be aware that the uploaded protocol will be made public.

The study protocol should be provided before the start of data collection. Where prior publication of the protocol could threaten the validity of the study or the protection of intellectual rights, a study protocol with redactions may be entered into the catalogue prior to the start of data collection. Further information about the requirements for the registration of PASS is available in the guideline on Good Pharmacovigilance Practices (GVP) module VIII.

Initial protocol [Add PDF, select a file from your computer] *One file only. 20 MB limit. Allowed types: pdf.*

Updated protocol [Add PDF, select a file from your computer] *One file only. 20 MB limit. Allowed types: pdf.*

7. Protocol link

URL [Free text with format: http://example.com] *The format used should be: http://example.com*

URL display text [Free text] *This is the text that will be displayed for the above URL (e.g., Study's final protocol)*

8. Regulatory

Was the study required by a regulatory body?* [Drop-down menu]

- □ Yes
- □ No

□ Unknown

Is the study required by a Risk Management Plan (RMP)?* [Drop-down menu]

□ EU RMP category 1 (imposed as condition of marketing authorisation)

□ EU RMP category 2 (specific obligation of marketing authorisation)

□ EU RMP category 3 (required)

□ Non-EU RMP only

□ Not applicable

If "EU RMP category 1 (imposed as condition of marketing authorisation)" or "EU RMP category 2 (specific obligation of marketing authorisation)" were selected in the last question, **Regulatory procedure number** [Free text] *Regulatory procedure number, applicable for RMP category 1 and 2 studies only*

9. Other study identifiers

This section can be used to provide identifiers used in other systems or databases (e.g.: NCT number, EudraCT number)

Other study ID [Free text]

Other study ID (links)

URL [Free text] *The format used should be http://example.com*

Link text [Free text] *This is the text that will be displayed for the above URL (e.g.: Link to Clinicaltrials.gov)*

URL [Free text] *The format used should be http://example.com*

Link text [Free text] *This is the text that will be displayed for the above URL (e.g.: Link to Clinicaltrials.gov)*

(…)

Step 2: Methodological Aspects

10. Study type

Study topic [Drop-down menu]

- □ Disease/health condition
- □ Herbal medicinal product
- □ Human medicinal product
- □ Medical device
- □ Medical procedure
- □ Other
- □ Veterinary medical product

Study topic, other [Free text] *If the study topic is not included in the above categories, please specify.*

Study type* [Drop-down menu]

- □ Clinical trial
- □ Non-interventional study
- □ Not applicable

If Clinical Trial, 11. Clinical trials

Clinical trial regulatory scope [Drop-down menu]

- □ Clinical trial not subject to marketing authorisation
- □ Post-authorisation interventional clinical trial
- □ Post-authorisation low-interventional clinical trial
- □ Pre-authorisation clinical trial

Clinical trial phase [Drop-down menu]

- □ None
- □ Human pharmacology (Phase I)
- □ Therapeutic confirmatory (Phase III)
- □ Therapeutic exploratory (Phase II)

□ Therapeutic use (Phase IV)

Clinical trial randomisation [Drop-down menu]

□ None

□ Randomised clinical trial

□ Non-randomised clinical trial

Clinical trial types [Drop-down menu]

□ Cluster randomised trial

□ Large simple trial

□ Low-interventional clinical trial

□ Pragmatic clinical trial

□ Single-arm trial

If Non-interventional Study, 11. Non-interventional study

Non-interventional study design [Drop-down menu]

□ Case-control

□ Case-only

□ Cluster design

□ Cohort

□ Cross-sectional

□ Ecological

□ Systematic review and meta-analysis

□ Other

Non-interventional study design, other [Free text, limited by 2000 characters] *If design of non-interventional study is 'Other', please specify.*

Scope of the study [Drop-down menu]

□ Assessment of risk minimisation measure implementation or effectiveness

- □ Disease epidemiology
- □ Drug utilisation
- □ Effectiveness study (incl. comparative)
- □ Feasibility analysis
- □ Healthcare resource utilisation
- □ Hypothesis generation (including signal detection)
- □ Method development or testing
- □ Patient reported outcomes
- □ Safety study (incl. comparative)
- □ Scoping review (including literature review)
- □ Validation of study variables (exposure outcome covariate)
- □ Other

Data collection methods [Drop-down menu]

- □ None
- □ Combined primary and secondary data collection
- □ No individual level data collected for the purpose of the study
- □ Primary data collection
- □ Secondary data collection

12. Study drug and medical condition

Name of medicine [Drop-down menu] *Brand names of the medicines studied*

Name of medicine, other [Free text] *If the medicinal product information (e.g.: brand name or active substance or ATC code) does not appear in the available look-ups in this section, please enter it here.*

Study drug International non-proprietary name (INN) or common name [Drop-down menu]

Anatomical Therapeutic Chemical (ATC) code [Drop-down menu]

Medical condition to be studied [Field with MedDRA codes]

Additional medical condition(s) [Free text] *If none of the above terms are applicable, please use this field to describe the (additional) medical condition studied.*

13. Population studied

Short description of the study population [Free text, limited by 10000 characters]

Age groups [Drop-down menu] *Select all that apply.*

- □ Adolescents
- □ Adult animal
- □ Adults
- □ Adults (18 to < 46 years)
- □ Adults (46 to < 65 years)
- □ Adults (65 to < 75 years)
- □ Adults (75 to < 85 years)
- □ Adults (85 years and over)
- □ Adults and elderly
- □ All
- □ Children
- □ Egg
- □ Elderly
- □ Embryonated egg
- □ In utero
- □ Infants and toddlers

- □ Neonate
- □ Paediatric Population
- □ Prepubertal children
- □ Preterm newborn infants
- □ Pubertal and postpubertal adolescents
- □ Term newborn infants
- □ Young animal
- □ Young animal/Newborn

Special population of interest [Drop-down menu] *Select all that apply.*

- □ Frail population
- □ Hepatic impaired
- □ Immunocompromised
- □ Nursing women
- □ Other
- □ Pregnant women
- □ Renal impaired
- □ Women of childbearing potential not using contraception
- □ Women of childbearing potential using contraception

Special population of interest, other [Free text] *If population of interest is 'Other', please specify which other population has been studied.*

Estimated number of subjects [Numerical value]

14. Study design details

Study design [Free text, limited by 300 characters] *Brief summary of the study design.*

Main study objective [Free text, limited by 10000 characters] *Short description of the main study objective.*

Setting [Free text, limited by 2000 characters] *Setting in terms of persons, place, time period and selection criteria, including a split by treatment arms/comparators or other relevant variable*

Comparators [Free text, limited by 2000 characters]

Outcomes [Free text, limited by 2000 characters]

Data analysis plan [Free text, limited by 2000 characters] *Brief summary of the analysis method (e.g. risk estimation, measures of risk, internal/external validity)*

Summary results [Free text, limited by 2000 characters] *A brief summary of the results of the study completion (from the abstract)*

15. Documents

Results tables *Multiple files. 20 MB limit. Allowed types: pdf.*

One PDF file with any results tables from the study. Please be aware that the uploaded document will be made public.

Study report *Multiple files. 20 MB limit. Allowed types: pdf.*

One PDF file and/or a weblink to the study report. Please be aware that the uploaded document will be made public.

URL [Free text] *This must be an external URL such as http://example.com.*

Link text [Free text]

Study, other information *Unlimited number of files can be uploaded to this field. 20 MB limit. Allowed types: pdf.*

Please upload any documents and/or insert any links to other relevant resources describing the study.

URL [Free text] *This must be an external URL such as http://example.com.*

Link text [Free text]

URL [Free text] *This must be an external URL such as http://example.com.*

Link text [Free text]

(...)

Study publications

URL [Free text] *This must be an external URL such as http://example.com.*

Link text [Free text]

URL [Free text] *This must be an external URL such as http://example.com.*

Link text [Free text]

(…)

Step 3: Data management

16. ENCePP Seal

ENCePP Code of conduct [Drop-down menu] *Is this study performed in line with the ENCePP Code of conduct?*

- □ None
- □ Yes
- □ No
- □ N/A

ENCePP Seal: *Are you requesting the ENCePP seal for this study?* [Toggle switch]

- □ Yes
- □ No

If "Yes" was selected in the last question

Please be aware that the uploaded documents will be made public.

Conflicts of interest of investigators *Multiple files. 20 MB limit. Allowed types: pdf.*

Composition of steering group and observers *Multiple files. 20 MB limit. Allowed types: pdf.*

Signed code of conduct *Multiple files. 20 MB limit. Allowed types: pdf.*

Signed code of conduct checklist *Multiple files. 20 MB limit. Allowed types: pdf.*

Signed checklist for study protocols *Multiple files. 20 MB limit. Allowed types: pdf.*

17. Data sources

Data source(s) [Drop-down menu with Data Sources registered in RWD Catalogues]
Names of data sources used in the study, registered in the catalogue. Select from the list.

Data source(s), other [Free text] *Enter the name of data sources if not included in the above look-up*

Data sources (types) [Drop-down menu]

- □ Omics
- □ Administrative data (e.g. claims)
- □ Clinical Trial
- □ Data from digital health wearables
- □ Disease registry
- □ Drug dispensing/prescription data
- □ Drug registry
- □ Drug utilisation data
- □ Electronic healthcare records (HER)
- □ Expanded access program (compassionate use)
- □ Laboratory data
- □ Non-interventional study
- □ Patient surveys
- □ Population registry
- □ Pregnancy registry
- □ Published literature
- □ Social media
- □ Spontaneous reporting system
- □ Other

If "Other" was selected in the last question, **Data sources (types), other** [Free text] *If the answer to 'Data sources (types)' is other, please specify.*

18. Use of a Common Data Model (CDM)

CDM mapping: *Were the data sources used in the study converted (ETL-ed) to a CDM (common data model)?* [Toggle switch]

□ Yes

□ No

CDM Mappings

If "Add Study CDM mapping" button was selected:

CDM name [Drop-down menu]

□ ConcepTION

□ Other CDM

□ OMOP

□ Sentinel Common Data Model

□ CDISC SDTM

□ PCORnet CDM

CDM name (other) [Free text]

CDM version [Free text]

19. Data quality specifications

Check conformance: *Was a check of the conformance of data (i.e., data are in the correct format/syntax) completed?** [Select an option]

□ Yes

□ No

□ Unknown

Check completeness: *Was a check of the completeness of data completed?** [Select an option]

□ Yes

□ No

□ Unknown

Check stability: *Was a check of the stability of data (e.g. codes) over time completed?** [Select an option]

□ Yes

□ No

□ Unknown

Check logical consistency: *Was a check of logical consistency of data completed?** [Select an option]

□ Yes

□ No

□ Unknown

20. Data characterisation

Data characterisation conducted: *Was a data characterisation or quality check process completed?** [Select an option]

□ Yes

□ No

□ Not applicable

□ Unknown

21. Procedures

Procedure of data extraction *One file only. 20 MB limit. Allowed types: pdf.*

22. Procedure of data extraction

URL [Free text] *This must be an external URL such as http://example.com.*

Link text [Free text]

Procedure of results generation *One file only. 20 MB limit. Allowed types: pdf.*

23. Procedure of results generation

URL [Free text] *This must be an external URL such as http://example.com.*

Link text [Free text]

***** End of questionnaire *****