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

You will need to apply online to add a Study

'Add a Study' Questionnaire

HMA-EMA RWD Catalogues

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

Automatic reminders will be sent in line with the dates provided in "Step 1: Administrative details" so that information are kept up to date.

The questionnaire comprises **21 questions** divided in **4 steps**: Administrative Details, Methodological Aspects, Data Management and Resources. 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*

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

Study description [Free text, limited by 2000 characters]

Study cancelled: *For studies that were planned but cancelled before commencement* [Toggle switch]

□ Yes

□ No

Study discontinued: *For studies that were initiated but terminated before completion* [Toggle switch]

□ Yes

□ No

2. Research institution and networks

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

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

If the 'Actual Date' field has already been filled in and you wish to edit it, please raise a ticket via the Contact Us page providing the Study ID/EUPAS number, the name(s) and new date(s) of any Actual Date fields you wish to edit and the reason for the change(s).

	Planned	**Actual**
Date when funding contract was signed*	[dd/mm/yyyy] __/__/____	[dd/mm/ yyyy] __/__/____
Study start date *Start of data collection date. For primary data collection, this is the date from which information on the first study subject is recorded. For secondary use of data, this is the data extraction start date (ref. FAQ 51). When the actual date is entered here, the status of the study will change from "planned" to "ongoing"*	[dd/mm/ yyyy] __/__/____	[dd/mm/yyyy] __/__/____
Data analysis start date*	[dd/mm/ yyyy] __/__/____	[dd/mm/ yyyy] __/__/____
Date of interim report, if expected*	[dd/mm/ yyyy] __/__/____	[dd/mm/ yyyy] __/__/____
Date of final study report* *When the actual date is entered here, the status of the study will change from "ongoing" to "finalised"*	[dd/mm/ yyyy] __/__/____	[dd/mm/ yyyy] __/__/____

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. Regulatory information

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

Regulatory procedure number [Free text] *Regulatory procedure number, applicable for RMP category 1 and 2 studies only*

7. 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)*

Step 2: Methodological Aspects

8. 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 study type is 'Not applicable', further details on the study type: [Free text]

If study type is 'Clinical Trial':

Clinical trial regulatory scope [Drop-down menu]

□ Clinical trial not part of marketing authorisation application or subject to marketing authorisation approval

□ Post-authorisation interventional clinical trial

□ Pre-authorisation clinical trial

Clinical trial phase [Drop-down menu]

□ 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 study type is '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)
- □ Evaluation of patient-reported outcomes
- □ Feasibility analysis
- □ Healthcare resource utilisation
- □ Hypothesis generation (including signal detection)
- □ Method development or testing
- □ Safety study (incl. comparative)
- □ Scoping review (including literature review)
- □ Validation of study variables (exposure outcome covariate)
- □ Other

Data collection methods [Drop-down menu]

- □ Combined primary data collection and secondary use of data
- □ No individual level data collected for the purpose of the study
- □ Primary data collection
- □ Secondary use of data

9. 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, ATC codes]

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.*

10. Population studied

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

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

- □ **All**
  - □ **In utero**
  - □ **Paediatric Population (< 18 years)**
    - Neonate
      - Preterm newborn infants (0 – 27 days)
      - Term newborn infants (0 – 27 days)
    - Infants and toddlers (28 days – 23 months)
    - Children (2 to < 12 years)
    - Adolescents (12 to < 18 years)
  - □ **Adult and elderly population (≥18 years)**
    - Adults (18 to < 65 years)
      - Adults (18 to < 46 years)
      - Adults (46 to < 65 years)
    - Elderly (≥ 65 years)
      - Adults (65 to < 75 years)
      - Adults (75 to < 85 years)
      - Adults (85 years and over)

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]

11. 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*

If study type is 'Clinical trial' or 'Not applicable', Interventions [Free text, limited by 2000 characters]

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)*

Step 3: Data management

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

- □ Yes
- □ No
- □ N/A

12. 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 sources, other [Free text] *Enter the name of data sources if not included in the above look-up*

Data sources (types) [Drop-down menu]

- □ Administrative healthcare data (e.g., claims)
- □ Biobank
- □ Birth registry
- □ Cancer registry
- □ Clinical trial

□ Congenital anomaly registry

□ Death registry

□ Disease registry

□ Drug prescriptions

□ Drug registry

□ Electronic healthcare records (EHR)

□ Expanded access program (compassionate use)

□ Induced terminations registry

□ Laboratory tests and analysis

□ Mobile Health (mHealth)

□ Non-interventional study

□ Patient surveys

□ Pharmacy dispensing records

□ Population registry

□ Pregnancy registry

□ Published literature

□ Social media

□ Spontaneous reports of suspected adverse drug reactions

□ Vaccination registry

□ 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.*

13. 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]

- □ BIFAP
- □ CDISC SDTM
- □ ConcepTION CDM
- □ CT cue Datamodel
- □ EUROCAT
- □ i2b2
- □ NorPreSS
- □ OMOP
- □ PCORnet
- □ PEDSnet
- □ Sentinel
- □ Vaccine Safety Datalink (VSD) Data Dictonary
- □ TrineTX
- □ EUROMEDICAT
- □ Other CDM

If 'Other CDM', CDM name (other) [Free text]

CDM mapping version [Free text]

14. 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

15. Data characterisation

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

- □ Yes
- □ No
- □ Not applicable
- □ Unknown

<u>If Data characterisation conducted = 'Yes':</u>

Data characterisation moment, *at what stages of the study were data characterisation steps or quality checks implemented?* [Select all that apply]

□ after data extraction

□ after extract-transform-load to a common data model

□ after creation of study variables

Data characterisation details, *provide a summary description of the data characterisation or quality check process* [Free text, limited by 1000 characters]

Data characterisation details, *provide a document and/or link describing the data characterisation or quality check process. Please be aware that the uploaded document will be made public.* *One file only. 20 MB limit. Allowed types: pdf.*

Data characterisation details (link)

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

Link text [Free text]

Data characterisation results (file), *provide results of the data characterisation or quality checks (e.g.: OMOP/OHDSI data quality dashboard or the Sentinel Common Data Model level 1-4 checks). These can be provided as a single document and/or link. Please be aware that the uploaded document will be made public.* *One file only. 20 MB limit. Allowed types: pdf.*

Data characterisation results (link)

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

Link text [Free text]

16. Procedures

Procedure of data extraction

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

Procedure of data extraction (link)

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

Link text [Free text]

Procedure of results generation

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

Procedure of results generation (link)

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

Link text [Free text]

Step 4: Resources

17. Protocol

Initial protocol *One file only. 20 MB limit. Allowed types: pdf.*

Updated protocol *One file only. 20 MB limit. Allowed types: pdf.*

18. Results

Study results *One pdf file with any results tables from the study. 20 MB limit. Allowed types: pdf.*

19. Report

Study report

One PDF file and/or a weblink to the study report.

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

Link text [Free text]

20. Other information

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]

21. Publications

Study publications *links to peer-reviewed papers reporting the study*

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

Link text [Free text]

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