15 February 2024
EMA/563896/2022
European Medicines Agency

List of metadata for the HMA-EMA Catalogues of real-world data sources and studies

Reviewed by European Network Data Board	28 April 2022
Adoption by Big Data Steering Committee	03 June 2022
Sent for information to Heads of Medicines Agencies	07 June 2022
Sent for information to EMA Management Board	07 June 2022
Sent for information to European Commission	07 June 2022
Version 2 published	15 February 2024

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1. Introduction

In line with the BDSG workplan and the EMRN Strategy to 2025 action on data discoverability, and through consultation with its stakeholders, EMA produced a list of metadata for describing real-world data (RWD) sources and studies.

The chosen metadata is included the HMA-EMA Catalogue of real-world data sources and studies, which contains information about existing real-world data sources (replacing the ENCePP Resource Database) and information about RWD studies (to replace and enhance the EU PAS Register).

The RWD Catalogues are intended to help regulators, pharmaceutical companies and researchers to identify and use such data when investigating the use, safety and effectiveness of medicines. The RWD Catalogues aim to:

- Facilitate the discoverability of adequate data sources to generate real-world evidence for regulatory purposes (e.g., identification of RWD data sources suitable for investigating a specific research question);
- Aid in the suitability assessment of data sources by providing clear and easy access to information from the study protocol and study report;
- Improve interoperability between studies and data sources;
- Improve transparency.

2. Data source metadata

2.1. Data source – Administrative details

1) Data source ID *<automatically generated>* (C.1.1)
2) Name of data source (as used in European projects) *: *<free text>* (C1.2)
3) Data source acronym: *<free text>* (C1.3)
4) Data holder *: *<lookup of institutions>* (C4.1)
5) Data source main contact *: *<First name> <Last name> <Email>* (M1.3) (M1.6)
6) Data source alternate contact email: *<First name> <Last name> <Email>* (M1.3) (M1.6)
7) Data source countries * (where data originates): *<select multiple:* ISO 3166-1 country codes> (C1.5)
8) Data source languages *: *<select multiple:* ISO 639 codes> (C6.2)
9) Data source regions (geographical regions that the data source covers): *<select multiple*: ISO 3166-2 country codes> (C1.5.1)
10) Date when the data source was first established: *<date>* (C4.5)
11) Data source time span: First collection *<date>* (C1.12), Last collection *<date>* (C1.13)
12) Data source website (where applicable, a dedicated website for the data source): *<free text | weblink>* (C11.1)
13) Data source publications (A list of peer-reviewed papers or documents describing the data source (validation, data elements, representativity) or its use for pharmacoepidemiologic research): *<free text| DOI or weblink>* (C11.2)
14) Data source qualification: if the data source has successfully undergone a formal qualification process (e.g., from the EMA, or ISO or other certifications) *<Yes | No>* (C3.1)
    If yes, description of the qualification(s) granted *<free text>* *(C3.1.1)*
15) Main financial support of the data source in the last three (3) years: *<select multiple>:* European public funding | Funding by own institution | Funding from industry or contract research | Funding from public-private partnership | Funds from patients organisations, charity and foundations | National, regional, or municipal public funding | Other> (C4.6)
16) Data source type *: *<select multiple:* Biobank | Birth registry | Cancer registry | Congenital anomaly registry | Death registry | Diagnostic tests or procedures reimbursement | Disease registry | Emergency care discharge records | Exemptions from co-payment | Hospital discharge records | Hospital inpatient records | Hospital outpatient visit records | Induced terminations registry | Other | Pharmacy dispensing records | Population dispensing records | Population registry | Primary care medical records | Registration with healthcare system | Specialist ambulatory care records | Spontaneous reporting of adverse drug reactions | Vaccination registry> (C5.1)
    If 'other', data source type: *<free text>* (C5.1.1)
17) Care setting for data source: *<select multiple:* Hospital inpatient care | Hospital outpatient care | Other | Primary care – GP, community pharmacist level | Primary care – specialist level (e.g. paediatricians) | Secondary care – specialist level (ambulatory)> (C1.14)

2.2. Data source – Data elements collected

18) The data source contains the following information *<Yes | No>*:

☐ Information on a specific disease (C1.10)

☐ Rare diseases (C6.12)

☐ Pregnancy and/or neonates (C1.9)

☐ Hospital admission and/or discharge (C6.10)

☐ ICU admission (C6.10.1)

☐ Cause of death (C6.11)

☐ Prescriptions of medicines (C6.13)

☐ Dispensing of medicines (C6.14)

☐ Advance therapy medicinal products (ATMP) (C6.16)

☐ Contraception (C6.17)

☐ Indication for use (C6.18)

☐ Medical devices (C6.20)

☐ Administration of vaccines (C6.19)

☐ Procedures (C6.21)

☐ Clinical measurements (C6.23)

☐ Healthcare provider (C6.24.1)

☐ Genetic data (C6.25)

☐ Biomarker data (C6.26)

☐ Patient-reported outcomes (e.g. quality of life) (C6.31)

☐ Patient-generated data (C6.27)

☐ Units of healthcare utilisation (C6.29)

☐ Unique identifiers for persons (C6.4)

☐ Diagnostic codes (C6.9)

☐ Medicinal product information (C6.15)

☐ Quality of life measurements (C6.15.2)

☐ Lifestyle factors (C6.8.1)

☐ Sociodemographic information (C6.7.1)

19) For data sources collecting specific disease information – disease(s) information collected *<free text | MedDRA>* (C1.10.1)

20) Medicinal product information collected: *<select multiple*: Active ingredient(s) | Batch number | Brand name | Dosage regime | Dose | Formulation | Package size | Route of administration | Strength> (C6.15.1)

21) Family linkage available in the data source permanently or can be created on an ad-hoc basis: *<select one:* None| Permanently | Adhoc (C6.6)

If 'permanently', family linkage available between the following persons: *<select multiple: Father-child* | Household | Mother-child | Sibling> (C6.2)

22) Sociodemographic information collected: *<select multiple:* Age | Country of origin | Deprivation index | Education level | Ethnicity | Gender | Health area | Living in rural area | Marital status | Not captured | Other | Pharmaceutical copayment | Sex | Socioeconomic status | type of residency> (C6.7)

23) Lifestyle factors collected: *<select multiple:* Alcohol use | Diet | Frequency of exercise | Not captured | Other | Tobacco use> (C6.8)

2.3. Data source - Quantitative descriptors

24) Population age groups: *<select multiple, as applicable>:* (C1.8)

☐newborn infants (0 to 27 days),
☐ infants and toddlers (28 days to 23 months),
☐ children (2 to 11 years),
☐ adolescents (12 to 17 years),
☐ adults (18 to 45 years),
☐ adults (46 to 64 years),
☐ adults (65 to 74 years),
☐ adults (75 to 84 years),
☐ adults (85 years and over),
☐ all age

25) Estimated percentage of the population covered by the data source in the catchment areas: *<free text | this field can also be used to include details and/or clarifications about the population and the population size that cannot be captures in other fields>* (C1.11.2)

26) Description of the population covered by the data source in the catchment area whose data are not collected (e.g. people who are registered only for private care): *<free text | this field can also be used to include details and/or clarifications about the population and the population size that cannot be captures in other fields>* (C1.11.1)

27) Population size (total number of unique individuals with records captured in the data source (most recent count)): *<number>* (C7.1)

28) Population size by age group: (C7.3)

<number> newborn infants (0 to 27 days),
<number> infants and toddlers (28 days to 23 months),
<number> children (2 to 11 years),
<number> adolescents (12 to 17 years),
<number> adults (18 to 45 years),
<number> adults (46 to 64 years),
<number> adults (65 to 74 years),
<number> adults (75 to 84 years),
<number> adults (85 years and over).

29) ***Active*** population size (total number of unique individuals alive and currently registered, i.e. where a record was created and not closed): *<number>* (C7.1.1)

30) ***Active*** population size by age group: *(C7.3.1)*

<number> newborn infants (0 to 27 days),
<number> infants and toddlers (28 days to 23 months),
<number> children (2 to 11 years),
<number> adolescents (12 to 17 years),
<number> adults (18 to 45 years),
<number> adults (46 to 64 years),
<number> adults (65 to 74 years),
<number> adults (75 to 84 years),
<number> adults (85 years and over).

31) Median observation time (years) between first and last available records for unique individuals captured in the data source: *<number>* (B6.3)
32) Median observation time (years) between first and last available records for unique ***active*** individuals (alive and currently registered) captured in the data source: *<number>* years (B6.3.1)

2.4. Data source – Data flows and management

33) Governance details - Documents or webpages that describe the overall governance, processes and procedure for data capture and management, data access, data quality check and validation results, utilisation for research purposes: *<add media | weblink>* (C2.3)
34) Biospecimen access: *<Yes | No>* (C2.13)

    If'yes', Biospecimen access conditions: *<free text>* (C2.13.1)

35) Access to subject details (can individual patients/practitioners/practices included in the data source be contacted?): *<Yes | No>* (C2.7)
36) Description of data collection (the process of collection and recording of data in the data source. This could include the tools used, such as surveys, or a description of the system that the originator uses to gather data and store it the data source: *<free text>* (C4.3)
37) Event triggering creation of a record in the data source (the event triggering for creation of *a record* in the data should be described (e.g.: hospital discharge, specialist encounter, dispensation of medicinal product, recording of a congenital anomaly). This refers in general to the creation of a record in the data source and not to the registration of a person: *<free text>* (C5.2)
38) Event triggering registration of *a person* in the data source: *<select multiple:* Birth | Disease diagnosis | Immigration | Insurance coverage start | Other | Practice registration | Residency obtained | Start of treatment> (C1.6)

    If 'other', event triggering registration of a person in the data source: *<free text>* (C1.6.1)

39) Event triggering ***de-***registration of a *person* in the data source: *<select one*: Death | Emigration | End of treatment | Insurance coverage end | Loss to follow up | Other | Practice deregistration> (C1.7)

    If 'other', the event triggering ***de***-registration of a person in the data source: *<free text>* (C1.7.1)

40) Linkage (is the data source described created by linkage of other data sources (pre-linked data source) and/or can the data source be linked to other data sources on an ad-hoc basis?): *<Yes | No>* (B.5.4)
41) Linkage description, pre-linked (description of the linkages that are currently available in the data (i.e. created by linkage of other data sources)): *<free text>* (B.5.1)
42) Linkage description, possible linkage (linkages to other data sources that are possible on an ad-hoc basis): *<free text>* (C1.5.1)
43) Pre linked (is the data source described created by the linkage of other data sources?): *<tick box>*
44) Names of linked data sources: *<look-up>* (B4.1)
45) Names of linked data sources if not available in the above look-up: *<free text>* (B4.1)
46) Linkage strategy: *<select one:* Deterministic | probabilistic | combination | other> (B5.2)

47) Linkage variable (the name and description of the linkage variable use e.g., patient ID, date of birth etc.): *<free text>* (B5.2.1)

48) Linkage completeness (the completeness of the linkage, as described as a percentage): *<free text>* (B5.3)

49) The following data management specifications apply for the data source: *<tick as applicable>*:

☐ Possibility of data validation (e.g.: access to original medical charts) (C9.5)

☐ Data source preservation (Are records preserved in the data source indefinitely?) (C8.5)

If 'no', data source preservation lengthy (years): *<number>* (C8.5.1)

☐ Approval for publication (is approval needed for publishing the results of a study using the data source?) (C2.9)

50) Informed consent for use of data for research: *<select one:* None | Not required | required for general use | required for all studies | required for intervention studies | waiver | Other> (C2.5)

If 'other', further details on the informed consent: *<free text>* (C2.5.1)

51) Data source refresh: *<select one:* none | specific month | Quarterly | Every 6 months | Yearly> (C8.2)

52) Data source last refresh: *<date>* (C8.3)

53) Common Data Model (CDM) mapping (has the data source been converted to a common data model?): *<Yes | No>* (D1.2.1.1)

54) CDM name: *<select one:* BIFAP | CDISC SDTM | ConcepTION CDM | CTcue Datamodel | EUROCAT | i2b2 | NorPreSS | OMOP | PCORnet | PEDSnet | Sentinel | Vaccine Safety Datalink (VSD) Data Dictionary | TrineTX | EUROMEDICAT | Other CDM> (D1.2)

If 'other', CDM used *<free text>* (D1.2.1)

55) Data source ETL status: *<select one:* Planned | Completed | In progress | Not ETL-ed> (B7.1)

56) Data source ETL CDM version: *<free text>* (B7.3)

57) Data source ETL frequency: *<number>* months (B7.5)

58) Data source ETL specifications (documents/URLs describing the mapping of the data source to the CDM, including codes and scripts to convert original data to CDM): *<document | weblink>* (B7.4)

2.5. Data source - Vocabularies

59) Medicinal product vocabulary: *<select multiple:* AIC | ART 57 | ATC | CNF | DIN | dm+d | EQDM | Gemscript | GTIN | IFA GmbH | MTHSPL | NDC | NDF | Not coded (Free text) | Other | RxNorm | SNOMED | SPN | WHO Drug | Z-index (G-standard)> (C6.15.1)

If 'other', what vocabulary is used: *<free text>* (C6.15.2)

60) Cause of death vocabulary: *<select multiple:* CCS | CPT | dm+d | EDC | HCPCS | Human Phenotype Ontology (HPO) | ICD | ICD-10 | ICD-10-CM | ICD-11 | ICD-9 | ICD-9-CM | ICPC | ICPC-1 |ICPC-2 | MedDRA | Not coded (Free text) | OMIM | OPCS | OPS | Orphacode | Orphanet Rare Disease Ontology (ORDO) | Other | Read | SNOMED | SNOMED CT> (C6.11.1)

If 'other', cause of death vocabulary used: *<free text>* (C6.11.2)

61) Quality of life measurements: *<select multiple:* 15D | AQoL-8D | EQ5D | HRQOL | HUI | MQOL | MQOL-E | Not captured | Not coded (Free text) | Other | QOLS | SF-36 | SF-6D | WHOQOL> (C6.28)

If 'other', quality of life measurements: *<free text>* (C6.28)

62) Prescription vocabulary: *<select multiple:* ALT | ATC | DrugBank | EphMRA | not coded | Other | RxNorm> (C6.13.1)

If 'Other', prescription vocabulary: *<free text>* (C6.13.2)

63) Dispensing vocabulary: *<select multiple*: ALT | ATC | DrugBank | EphMRA | not coded | Other | RxNorm> (C6.14.1)

If 'Other', dispensing vocabulary: *<free text>* (C6.14.2)

64) Indication vocabulary: *<select multiple:* CCS | CPT | dm+d | EDC | HCPCS | Human Phenotype Ontology (HPO) | ICD | ICD-10 | ICD-10-CM | ICD-11 | ICD-9 | ICD-9-CM | ICPC | ICPC-1 |ICPC-2 | MedDRA | Not coded (Free text) | OMIM | OPCS | OPS | Orphacode | Orphanet Rare Disease Ontology (ORDO) | Other | Read | SNOMED | SNOMED CT> (C6.18.1)

If 'other', indication vocabulary: *<free text>* (C6.18.2)

65) Procedures vocabulary: *<select multiple:* CCS | CPT | dm+d | EDC | HCPCS | Human Phenotype Ontology (HPO) | ICD | ICD-10 | ICD-10-CM | ICD-11 | ICD-9 | ICD-9-CM | ICPC | ICPC-1 |ICPC-2 | MedDRA | Not coded (Free text) | OMIM | OPCS | OPS | Orphacode | Orphanet Rare Disease Ontology (ORDO) | Other | Read | SNOMED | SNOMED CT> (C6.22)

If 'other', procedure vocabulary: *<free text>* (C6.22)

66) Genetic data vocabulary: *<select multiple:* EGO | FG | GO | HGNC | HGVS | OGG | OMIM | Other | PHARE | SOPHARM> (C6.25.1)

If 'other', genetic data vocabulary: *<free text>* (C6.25.1)

67) Biomarker data vocabulary: *<select multiple*: BMO | FOBI | HPO | Other | SMASH> (C6.26.1)

If 'other', Biomarker vocabulary: *<free text>* (C6.26.1)

68) Diagnosis / medical event vocabulary: *<select multiple:* CCS | CPT | dm+d | EDC | HCPCS | Human Phenotype Ontology (HPO) | ICD | ICD-10 | ICD-10-CM | ICD-11 | ICD-9 | ICD-9-CM | ICPC | ICPC-1 |ICPC-2 | MedDRA | Not coded (Free text) | OMIM | OPCS | OPS | Orphacode | Orphanet Rare Disease Ontology (ORDO) | Other | Read | SNOMED | SNOMED CT> (C6.9.1)

If 'other', diagnosis / medical event vocabulary: *<free text>* (C6.9.1)

3. Study metadata

3.1. Study – Administrative details

1) *(EU PAS)* EU PAS register number: *<automatically generated number>* (F2.2)
2) *(EU PAS)* Official study title and acronym *: *<free text>* (F1.2)
3) *(EU PAS)* Study description: *<free text>* (F10)
4) DARWIN EU® study: *<Yes | No>* (F9.5)
5) *(EU PAS)* Study status: *<automatically updated based on dates given in the 'study timeline' step:* planned | ongoing | finalised> (F11)
6) Institution conducting the study: *<lookup of institutions>* (F1.3)
   Additional institutions if not in the list: *<free text>* (F1.7)
7) Network conducting the study (if applicable): *<lookup of networks>* (F1.8)
   Additional networks if not in the list: *<free text>* (F1.8)
8) Study institution contact *: *<First name> <Last name> <Email>* (F1.4) (F1.5)
9) *(EU PAS)* Primary lead investigator name *: *<First name> <Last name>* (F12)
   Primary lead investigator ORCID: *<number>* (F1.6)
10) *(EU PAS)* Study timelines: initial administrative steps, progress reports and final report:

	Planned	Actual
Date when funding contract was signed *	*<date>*(F19)	*<date>* (F19.1)
Study start date (protocol finalisation) *	*<date>* (F20)	*<date>* (F20.1)
Data analysis start date	*<date>* (F21)	*<date>* (F21.1)
Date of interim report, if expected	*<date>* (F22)	*<date>* (F22.1)
Date of final study report*	*<date>* (F23)	*<date>* (F23.1)

11) *(EU PAS)* Study countries in which this study is being conducted *:*<select multiple:* ISO 3166-1 country codes> (F1.9)
12) Source of funding: *<select multiple*: EMA | EU institutional research programme | National competent authority (NCAs) | No external funding | Non for-profit organisation (e.g., charity) | Non-EU institutional research programme | Other | Other public funding (e.g.: hospital, university) | Pharmaceutical company and other private sector> (F8.8)
   More details on source funding. If source funding is a pharmaceutical company, company name should be added in this field: *<free text>* (F8.8.1)
13) Protocol link: A link to the latest version of the protocol, if published *<weblink>* (F2.1)
   Protocol document *<uploaded document>* (F2.3)
14) *(EU PAS)* Study required by a regulator *: *<select one:* Yes | No | Uknown> (F14)
15) *(EU PAS)* Is the study required by a Risk Management Plan (RMP) *: *<select one*: 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> (F14.1)

16) *(EU PAS)* Regulatory procedure number (RMP category 1 and 2 studies only): *<free text>* (F14.2)

17) *(EU PAS)* Other study registration identification numbers and URLs as applicable: *<free text> (F1.1.1)*

Other study (links): *<weblink>*

3.2. Study – Methodological aspects

18) Study topic: *<select multiple:* Disease/health condition | Herbal medicinal product | Human medicinal product | Medical device | Medical procedure | Other | Veterinary medicinal product> (F8.1)

If 'other', further details on the study topic: *<free text>* (F8.1.1)

19) Study type *: *<select one:* Clinical trial | Non-interventional study | Not applicable> (F8.2)

If 'Not applicable', further details on the study type: *<free text>* (F8.2.1)

If Study type = clinical trial

20) Clinical trial regulatory scope: *<select multiple:* clinical trial not subject to marketing authorization | post-authorisation interventional | clinical trial post-authorization low-interventional | clinical trial pre-authorisation clinical trial> (F8.2.2)

21) Phase of the clinical trial: *<select one:* None | Human pharmacology (Phase I) | Therapeutic confirmatory (Phase II) | Therapeutic exploratory (Phase III) | Therapeutic use (Phase IV)> (F8.4)

22) Clinical trials randomisation: *<select one:* None | Randomised clinical trial | Non-randomised clinical trial> (F8.3)

23) Clinical trial types: *<select multiple:* Cluster randomised trial | Large simple trial | Low-interventional clinical trial | Pragmatic clinical trial | Single-arm trial> (F8.3.1)

If Study type = non-interventional study

24) Non-interventional study design: *<select multiple:* Case-control | Case-only | Cluster design | Cohort | Cross-sectional | Ecological | Other | Systematic review and meta-analysis> (F8.3.2)

If 'other', specify design of non-interventional study: *<free text>* (F8.3.2.1)

25) Scope of the study: *<select multiple:* 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 | Other | Patient reported outcomes | Safety study (incl. comparative) | Scoping review (including literature review) | Validation of study variables (exposure outcome covariate)> (F8.6)

If 'other', further details on the scope of the study: *<free text>* (F8.6.1)

26) Data collection methods: *<select one:* None | Combined primary and secondary data collection | No individual level data collected for the purpose of the study | Primary data collection | Secondary data collection> (F8.5)

27) Name of medicine (brand names of the medicines studies): *<Look-up | select multiple>* (F17)

If 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: *<free text>*

28) *(EU PAS)* Study drug International non-proprietary name (INN) or common name *<select one | INN list>* (F16)
29) *(EU PAS)* Anatomical Therapeutic Chemical (ATC) code *<select multiple | ATC code>* (F15)
30) *(EU PAS)* Medical condition to be studied *<MedDRA list>* (F18)
31) *(EU PAS)* Additional medical condition(s) *<free text>* (F18.1)
32) *(EU PAS)* Population studied: A short description of the study population: *<free text>* (F2.5)
33) *(EU PAS)* Age groups: *<select multiple:* newborn infants (0 to 27 days) | infants and toddlers (28 days to 23 months) | children (2 to 11 years) | adolescents (12 to 17 years) | adults (18 to 45 years) | adults (46 to 64 years) | adults (65 to 74 years) | adults (75 to 84 years) | adults (85 years and over) | all ages*>* (F2.5.1)
34) *(EU PAS)* Special population of interest: *<select multiple:* 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*>* (F8.9)
    If 'other', specify which other population has been studied: *<free text>* (F8.9.1)
35) *(EU PAS)* Estimated number of subjects: *<number>* (F2.5.2)
36) Study design (brief summary of the study design): *<free text>* (F2.13)
37) Main study objective (short description of the study objective): *<free text>* (F8.10)
38) Setting (setting in terms of persons, place, time period and selection criteria, including a split by treatment arms/comparators or other relevant variables): *<free text>* (F2.11)
39) If study type is 'clinical trial', Interventions: *<free text>* (F2.6)
40) Comparators: *<free text>* (F2.7)
41) Outcomes: *<free text>* (F2.8)
42) Data analysis plan (brief summary of the analysis method (e.g. risk estimation, measures of risk, internal/external validity)): *<free text>* (F2.12)
43) Summary results (brief summary of the results of the study completion (from the abstract)) *<free text>* (F6.3)
    Results tables *<uploaded document>* (F6.4)
    Study report: *<uploaded document | weblink>* (F7.2)
44) Study, other information (list of URLs to other relevant resources describing the study *and/or* files as applicable): *<uploaded document | weblink>* (F7.3)
45) Study publications (links to peer-reviewed papers reporting the study) *<weblink>* (F7.1)

3.3. Study – Data management

46) *(EU PAS)* ENCePP Code of Conduct (is the study performed in line with the ENCePP Code of conduct?) *<None | Yes | No | N/A> (F9.3.2)*
47) ENCePP Seal: are you requesting the ENCePP seal for this study? *<Yes | No> (F9)*
48) *for Admin only:* Grant the ENCePP Seal for this study *<Yes | No> (F9)*
49) *(EU PAS)* ENCePP Seal relevant documents:

☐ Conflicts of interest of investigators *<uploaded document> (F9.1)*
☐ Composition of steering group and observers *<uploaded document> (F9.2)*
☐ Signed code of conduct *<uploaded document> (F9.3)*

☐ Signed code of conduct checklist *<uploaded document>* *(F9.3.1)*

☐ Signed checklist for study protocols *<uploaded document>* *(F9.4)*

50) Data sources (names of data sources used in the study, registered in the catalogue): *<lookup of data sources>* (F3.4)

Data sources, if not available in the list above: *<free text>* (F3.4)

51) Data sources (types): *<select multiple*: 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 (EHR) | Expanded access program (compassionate use) | Laboratory data | Non-interventional study | Omics | Other | Patient surveys | Population registry | Pregnancy registry | Published literature | Social media | Spontaneous reporting system> (F8.7)

If 'other', specify data sources type: *<free text>* (F8.7.1)

52) CDM mapping: were data sources in the study converted (ETL-ed) to a CDM (common data model)? *<Yes | No>* (F4.1)

CDM name: *<select one:* BIFAP | CDISC SDTM | ConcepTION CDM | CTcue Datamodel | EUROCAT | i2b2 | NorPreSS | OMOP | PCORnet | PEDSnet | Sentinel | Vaccine Safety Datalink (VSD) Data Dictionary | TrineTX | EUROMEDICAT | Other CDM> (F4.2)

CDM mapping version or version date: *<free text>* (F4.3)

Data quality specifications

53) Check conformance (was a check of the conformance of data (i.e., data are in the correct format/syntax) completed? * *<Yes | No | Unknown>* (F5.3)

54) Check completeness (was a check of the completeness of data completed?) *: *<Yes | No | Unknown>* (F5.4)

55) Check stability (was a check of the stability of data (e.g. codes) over time completed?) *: *<Yes | No | Unknown>* (F5.5)

56) Check logical consistency (was a check of logical consistency of data completed?) *: *<Yes | No | Unknown>* (F5.6)

57) Data characterisation conducted (was a data characterisation or quality check process completed?)*: *<Yes | No | Not applicable | Unknown>* (F5.1)

If 'yes', Data characterisation moment (at what stages of the study were data characterisation steps or quality checks implemented?): *<select multiple*: after data extraction | after extract-transform-load to a common data model | after creation of study variables> (F5.2)

If 'yes', Data characterisation details (provide a summary description of the data characterisation or quality check process): *<free text | uploaded document | weblink>* (F5.7)

If 'yes', Data characterisation results (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)): *<uploaded document | weblink>* (F5.8)

58) Procedure of data extraction: *<uploaded document | weblink>* (F6.1)

59) Procedure of result generation: *<uploaded document| weblink>* (F6.2)

4. Institution metadata

1) Institution ID: *<automatically generated>* (A1.1)
2) Institution full name and acronym *: *<free text>* (A1.2)
3) Institution country *: *<select multiple:* ISO 3166-1 country codes> (A1.5)
4) Type of institution (the sector where the institution operates): *<select one:* None | Educational Institution | EEA National Competent authority | EU Institution/Body/Agency | Healthcare payer | Hospital/Clinic/Other health care facility | Laboratory/Research/Testing facility | Non-EU Institution/Body/Agency | Non-EEA National Competent authority | Non-Pharmaceutical company | Other | Other EEA National Competent Authorities | Patient organisation/association | Pharmaceutical association/federation | Pharmaceutical company | Regulatory Authority> (A1.4)
5) Institution role (roles of the institution in connection with data sources or studies in the catalogues): *<select multiple:* Data holder | Data provider | Other | Researcher> (A1.8)
6) Institution website: *<weblink>* (A1.6)

Institution details

7) Collecting data directly from individual patients/respondents (does the institution have experience in collecting data directly from individuals or respondents?): *<Yes | No>*
8) Research directly funded by pharmaceutical companies (in principle, would the institution care out research that is funded by pharmaceutical companies?): *<Yes | No>*
9) ENCePP Partner (do you want to apply to become an ENCePP partner?): *<Yes | No>* (A2.5)
10) Institution main contact person *: *<First name> <Last name> <Email>* (A1.7.1)
11) Alternate contact*: <First name> <Last name> <Email>*

5. Network metadata

1) Network ID: *<automatically generated>* (E1.1)
2) Network name and Acronym *: *<free text>* (E1.2)
3) Network countries *: *<select multiple:* ISO 3166-1 country codes> (E1.9)
4) Network website: *<weblink>* (E1.4)
5) Network description: *<free text>* (E1.13)
6) Primary therapeutic/disease areas? *<select multiple*: Anaesthesia | Cardiovascular diseases | Congenital Malformations | Disorders of the central nervous system | Ear, nose and oropharynx disorders | Endocrine disorders | Eye disorders | Gastrointestinal tract | Geriatrics | Gynaecology | Immunological products and vaccines | Immunosuppression | Infectious diseases | Liver disease | Malignant disease | Medical devices | Musculoskeletal and joint diseases | Neonatology | Nutrition and blood | Osteoporosis | Other | Paediatrics | Poisoning/Overdose | Pregnancy | Psychiatry | Renal impairment | Respiratory diseases | Skin disorders | Urinary tract disorders> (E1.12)
7) Source of funding: *<select multiple*: EMA | EU institutional research programme | National competent authority (NCAs) | No external funding | Non for profit organisation (e.g. charity) | Non-EU institutional research programme | Other | Other public funding (e.g.: hospital, university | Pharmaceutical company and other private sector> (E1.11)
8) ENCePP partner (do you want to apply to become an ENCePP partner?): *<Yes | No>* (E1.10)
9) Network main contact person *: *<First name> <Last name> <Email>* (E1.5)
10) Alternate contact person: *<First name> <Last name> <Email>* (E1.5)
11) Which institution are part of this network: *<select multiple from lookup of institutions>* (E1.7)
    Add an institution if not in the list: *<free text>* (F1.7)

6. Text and format conventions used