Good practice guide - Revision of the final metadata list based on MINERVA Project findings

Version 2.0 02 December 2021

Document overview

This document is an update of the Final Metadata List (June 2021), and is an appendix of the Good Practice Guide. The following additions have been made to this document on top of the original final metadata list:

1. Two new metadata tables "F8 Study - Data sources" and "F9 - Study - Data banks" have been added to the catalogue. These tables indicate the metadata variables from the full metadata list that are recommended to be additionally populated in a study-dependent manner.

2. A reviewed prioritisation of the metadata variable list is indicated in the Full metadata list sheet.

3. Recommendations for changes in the names and descriptions have been made in the Full metadata list sheet, based on experiences of the pilot catalogue implementation and further review. The recommended changes and their rationale are described in a column in the Full metadata list sheet "Updates made to variable in the Best Practice Guide and additional lessons learned". The original names and descriptions are preserved in the individual metadata table sheets to permit comparison between the Final metadata list

(June 2021) and the recommended changes (December 2021).
4. Two additional columns are added to the full metadata list sheet to indicate the unit of observation (the definition of this is found below) of each metadata variable in the catalogue, and an indicator variable (letter "b") to show that a metadata table is recommended to be split into a subtable, because the subtable contains metadata variables with a

different unit of observation from the main table. This is a key recommendation to support improved implementation of the metadata list in a catalogue.

5. Additional columns have been added in the full metadata list sheet to indicate the variables that were implemented in the proof-of-concept (POC) catalogue, and the names of the tables and columns to which they are mapped in the catalogue implementation.

### Glossary

Terms	Definition
ATC	Anatomical Therapeutic Chemical
Catalogue	The set of standardised tools used to access, search, and visualise metadata to illustrate each data bank and data source.
Catalogue domain	The catalogue is envisioned to consist of six main domains of metadata, organised in subtables: <i>Institution, Network, Data source, Data bank, Common data model, and Study</i> .
Catalogue table	An underlying table in the envisioned metadata catalogue comprising a collection of multiple metadata variables. Each domain of the catalogue consists of one or more catalogue tables.
Common data model (CDM)	Common structure and format for data that allows for an efficient execution of programs against local data.
Contributor	An institution that contributes content to the metadata catalogue.
Data access provider (DAP)	An organisation authorised to obtain access to and/or receive extracts from one or multiple data banks (e.g., for the purpose of research or surveillance).
Data bank	A data collection sustained by a specified organisation, which is the data originator. The data bank is defined by the underlying population that can potentially contribute records to it, the prompt that leads to creation of a record in the data bank, and the data model of the data bank.
Database	A data structure that stores organised information. Most databases contain multiple tables, which may each include several different fields. A database can host data from one or more data banks.
Data characterisation	The summarisation of features of data, including quantitative measures of completeness and quality.
Data controller (Joint Controllers)	The organisation(s) that determine(s) the purposes for which and the means by which personal data are processed. Joint controller is a definition of the GDPR; the qualification as joint controllers may arise when more than one actor is involved in the processing.
Data originator	An organisation that sustains the collection of records in a data bank (e.g., a healthcare payer).
Data processor	An organisation that processes personal data only on behalf of the data controller. The data processor is usually a third party external to the data controller.
Data source	All the data banks referring to the same or partially overlapping underlying population that a given DAP can access (or receive extracts from) and link to one another at an individual level for the purpose of a study.
Extract, transform, load (ETL)	A repeatable process for converting data from one format to another, such as from a source format to the CDM. In this process, mappings to the standardised dictionary are added. It is typically implemented as a set of automated scripts.
ICD	International Classification of Diseases
ID	Identifier
Institution	An organisation connected to one or more data sourcessuch as a DAP, a data originator, a data controller, a data processor, or an organisation with analytic expertisethat may contribute to the catalogue.
Metadata	A set of data that describes and gives information about other data. More specifically, information describing the generation, location, and ownership of the data set; key variables; and the format (e.g., coding, structured versus not) in which the data are collected is needed to enable accurate identification and qualification of the exposure and outcome information available. In addition, metadata also include the provenance and time span of the data, clearly documenting the input, systems, and processes that define data of interest. Finally, metadata include details on the storage, handling processes, access, and governance of data.
PAES	Post-authorisation efficacy study
PASS	Post-authorisation safety study
POC	Proof of concept. This refers to the proof-of-concept EMA MINERVA catalogue
Prompt	An event that prompts the generation of a record in a data bank.
Standardised dictionary	A tool containing a list of variables and their definitions to enable transparent and consistent content across disparate observational data sources and allows efficient and reproducible observational research.
Underlying population	The population of individuals who can potentially contribute information to a data source or data bank. This may be a geographic population or a disease-specific or condition-specific population within a geographic area, in the case of a registry.
Unit of observation	The type of object that is being described in the metadata catalogue. This may be an institution, a data bank, a data source, a CDM, a network or a study. It may also be a combination of more than one of these. For example, a metadata variable may have the unit of observation Institute-Data source (A,B). This means that the variable needs to be populated by a contributor per data source. A metadata variable with unit of observation Data source-Data bank (B,C) should be populated individually for every data bank in a data source. The unit of observation of every metadata variable is designated in the sheet "Full metadata list".
Vocabulary	Standardised medical terminologies; may be an international standard (e.g., International Classification of Diseases, Anatomical Therapeutic Chemical) or a country-specific or region-specific system or modification.

# Catalogue structure and links between tables

Each sheet in this document contains a metadata table that will be represented in the metadata catalogue. The metadata tables may contain IDs that are repeated across tables in the same catalogue section, or across catalogue sections. In the catalogue, these variables need to be entered only once, and herein represent where the tables in the catalogue will link to one another. ID numbers will be generated on first entry for an institution, data source, data bank, CDM, network, or study.

In the special case where a data source is composed of a single data bank, rules will be in place to automatically populate equivalent metadata variables in the data source tables with information entered in the data bank tables.

The final sheet of the document contains a full list of the metadata variables, labelled by catalogue domain, catalogue table, and metadata type. Where the same metadata variable is found in multiple tables (for example, in both the data source and data bank domains), the relation between metadata in these two sections is provided, as well as (where applicable), a rule by which entry of data for this variable in one table in the catalogue leads to automatic population of the same variable in another table.

# Prioritisation of metadata variables

This document presents an extensive list of metadata variables recommended for collection. The metadata are separated into two categories: **priority** metadata and additional metadata.

Priority metadata (hold): Priority metadata to be collected, providing critical information. These labels reflect the original designation of priority variables (June 2021). Following

Priority metadata (bold): Priority metadata to be collected, providing critical information. These labels reflect the original designation of priority variables (June 2021). Following further review by the EMA, an updated classification of the priority of metadata is provided in the sheet "Full metadata list".

Additional metadata: If possible, these additional metadata variables are recommended to be collected in addition to the priority variables.

# Catalogue Entry - Metadata on the metadata

The Catalogue domain contains metadata that will be recorded on creation of any entry to the catalogue. This "metadata on metadata" captures the provenance of metadata in the catalogue and may be implemented in a catalogue alongside individual metadata entries (as a time stamp) or presented as an overall log of when entries are made in the catalogue. In this document, it is listed as a standalone table. These metadata variables will be integrated in the proof-of-concept catalogue by the automated creation of a time stamp for each metadata entry, as well as a label to describe who entered the metadata. In a future implementation, these metadata could be created when contributors log into the catalogue with a verified account, and a historical record of entries could be supported to facilitate version control.

### Overview of catalogue tables

Catalogue table	Description	Table linked	Identifier linked
M1 Catalogue - entry	Metadata describing who entered information in the catalogue and when		
A1 Institution - role	Role of institution in studies and expertise	E1 - Network - overview	A1.1 - Institution ID
A2 Institution - data sources and data banks	Data sources and data banks to which the institution is connected. If the institution is a DAP, details on access to (an extract of) the data source or data bank is recorder, as well as whether only a subset of the underlying population can be accessed	B1 - Data source - underlying population, C1 - Data bank - underlying population	B1.1 - Data source ID, C1.1 - Data bank ID
A3 Institution - access contracts	Description of how access is permitted for DAPs and timing of access	A2 - Institution - data sources and data banks	B1.1 - Data source ID
A4 Institution - studies	List of relevant studies connected to data sources and data banks in the catalogue conducted by the institution	F1 - Study - institutions	A1.1 - Institution ID
B1 Data source - underlying population	Description of the population that can potentially be captured in the data source	A2 - Institution - data sources and data banks, C1 - Data bank - underlying population	source ID, C1.1 - Data bank ID
B2 Data source - access	access conditions for the data source	A2 - Institution - data sources and data banks; C2 - Data bank - data access	
B3 Data source - qualification	This table contains metadata describing any qualifications that the data source has successfully undergone, such as EMA qualification.		
B4 Data source - data banks	List of the data banks that comprise the data source and summary information of their contents	C5 - Data bank - prompt, C6 - Data bank - data model and content	B4.1 - Data banks, B1.1 - Data source ID, C1.1 - Data bank ID
B5 Data source - linkage	Description of existing linkages between data banks in the data source		
B6 Data source - quantitative descriptors B7 Data source - ETL	Numerical summaries describing data source population  Existing extract-transform-load specifications for mapping of data source to a	D1 - CDM - general, F4 - Study -	D1.1 - CDM ID, B1.1 - Data
B8 Data source - studies	CDM  List of relevant studies conducted using the data source	mappings F3 - Study - data sources and	source ID , F1.1 - Study ID B1.1 - Data source ID , F1.1 -
	-	data banks	Study ID
B9 Data source - publications	List of publications relevant to the data source	F3 - Study - data sources and data banks, F7 - Study - publications	B1.1 - Data source ID , F1.1 - Study ID
C1 Data bank - underlying population		B1 - Data source - underlying population	B4.1 - Data banks, B1.1 Data source ID, C1.1 - Data bank ID
C2 Data bank - access	List of data access providers of the data bank and information pertaining to access conditions for the data bank	A2 - Institution - data sources and data banks, B2 Data source - access	B1.1 - Data source ID, C1.1 - Data bank ID
C3 Data bank - qualification	This table contains metadata describing any qualifications that the data bank has successfully undergone, such as EMA qualification.		
C4 Data bank - originator	Information on the institution or body that sustains or maintains the collection of records in the data bank		
C5 Data bank - prompt	Information on which event(s) trigger the creation of a record in the data bank	B4 Data source - data banks	B4.1 - Data banks, B1.1 - Data source ID, C1.1 - Data bank ID
C6 Data bank - data model and contents	Description of the data model (dictionary) of the data bank, including vocabulary	B4 Data source - data banks	B4.1 - Data banks, B1.1 - Data source ID, C1.1 - Data bank ID
C7 Data bank - quantitative descriptors	Numerical summaries describing data bank population		
C8 Data bank - updates and lag time C9 Data bank - quality	Information on the regularity of updates and time lags  Qualitative descriptions of quality and completeness and quantitative		
· · · ·	information on completeness	F2 Study data acurace and	C1.1 Data bank ID F1.1
C10 Data bank - studies	List of relevant studies conducted using the data bank		C1.1 - Data bank ID , F1.1 - Study ID
C11 Data bank - publications	List of publications relevant to the data bank and relevant applications	F3 - Study - data sources and data banks, F7 - Study - publications	C1.1 - Data bank ID , F1.1 - Study ID
D1 Common data model - general	General description of the common data model, including description of related tools	B7 Data source - ETL, F4 Study - mappings to CDM	D1.1 - CDM ID, B1.1 - Data source ID , F1.1 - Study ID
D2 Common data model - vocabulary	Vocabularies used in the common data model	Ad Institution note	Ad d. Institution ID
E1 Network - overview F1 Study - institutions	Description of networks/consortia linking to institutions and studies  List of institutions involved in the study	A1 - Institution - role A4 - Institution - studies	A1.1 - Institution ID A1.1 - Institution ID
F2 Study - protocols	Links to protocols related to the study	74 - Montation - Stadios	ATT - Institution ID
F3 Study - data sources and data banks	List of data sources and data banks included in the study	B8 Data source - studies, C10 Data bank - studies, F5 Study - data characterisation, F6 Study - results	B1.1 - Data source ID, C1.1 - Data bank ID , F1.1 - Study ID
F4 Study - mappings to CDM	List of mappings that have been done to CDMs in the study, and related ETL specifications	B7 Data source - ETL, D1 Common data model - general	D1.1 - CDM ID, B1.1 - Data source ID , F1.1 - Study ID
F5 Study - data characterisation	Quantitative descriptors of the completeness and indicators (e.g., level 1-3 checks on the common data model instance)		,
F6 Study - results	List of any results generated by the study		
F7 Study - publications	List of any publications generated by the study	B9 Data source - publications, C11 Data bank - publications	B1.1 - Data source ID, C1.1 - Data bank ID , F1.1 - Study ID
F8 Study - data sources	This table lists all the variables that may have a study-specific entry for a data source (i.e. an entry created at the time of conduct of a study, populated, for example, by an interoperable link between the metadata catalogue and the EU PAS register). This entry could be created in parallel to a study-independent entry.	·	
F9 Study - data banks	This table lists the variables that may have a study-specific entry for a data bank (i.e. an entry created at the time of conduct of a study, populated, for example, by an interoperable link between the metadata catalogue and the EU PAS register). This entry could be created in parallel to a study-independent entry.		

CDM = common data model; EMA = European Medicines Agency; ETL = extract, transform, load.

Classified as internal/staff contractors by the European Medicines Agency

# Metadata category: Catalogue - entry

\* This is a representation of the metadata that will be created on entry of metadata by a contributor to the catalogue.

A full description of how these metadata will be created is provided in the main report, section 4.1.1.

Var ID	Var name	Description	Standards	Entry
M1.1	Creation date	Date of creation of first entry	DDMMYYYY	Automated entry, only on first entry
M1.2	Date of last update	Date on which the entry to the catalogue was made	DDMMYYYY	Automated entry
M1.3	Name of contact person	Person responsible for the individual entry	Free text	Manual entry or automated entry using information from user account
M1.4	Institution ID	A persistent identifier for an institution. This may be created by the catalogue maintainer on first entry of an institution. It provides links across tables.	Should take values within A1.1	Manual entry or automated entry using information from user account
M1.5	Type of contact	Role within the institution	Administrative/scientific/other	Manual entry or automated entry using information from user account
M1.5.1	Type of contact, other	If other, free text description of type of contact	Free text	Manual entry or automated entry using information from user account
M1.6	Email contact	Email address of person responsible for the entry	Free text; must take form "prefix@domain"	Manual entry or automated entry using information from user account
M1.7	Tables updated	List of the data tables that were changed in the update. Select one or more of the following	A1/A2/A3/A4/B1/B2/B3/B4/B5/B6/B7/B8/B9/C1/C2/C3/C4/C5/C6/C7/C8/C9/C10/C11/D1/D2/E1/F1/F2/F3/F4/F5/F6/F7	Manual entry or automated entry depending on catalogue software
M1.8	Reason for update	List of the reasons for the update. Select one or more of the following	New entry/metadata needed update following changes/correction of prior entry/other	Manual entry
M1.8.1	Reason for update other	If other, free text description of the reason for the update	Free text	Manual entry
M1.8.2	Update description	Description of changes made in the update	Free text	Manual entry

ID = identifier; ETL = extract-transform-load; CDM = common data model

### Metadata category: Institution - role

Var ID	Var name	Description	Standards	Entry
A1.1	Institution ID	A persistent identifier for an institution. This may be created by the catalogue maintainer on first entry of an institution. It provides links across tables and between catalogues.		Manual entry or an existing identifier or creation by the catalogue maintainer on first entry of the institution to the catalogue.
A1.2	Institution full name	Official name of the institution or organisation as used in EU projects. Free text		Manual entry
A1.3 A1.4	Institution acronym Type of organisation	Official acronym of the institution, if applicable. In which sector is the institution? Select one of the following	Free text Academic institution/civic authority/government agency/healthcare payer/network of primary care practices/non-profit organisation/pharmaceutical industry/private organisation/public health authority/research centre/statistical authority	Manual entry Manual entry
A1.4.1 A1.5	Type of organisation, other Institution country	If other, description of type of organisation.  Country in which organisation head office or coordinating centre is located.	Free text Select from list of countries, links to ISO 3166-1 country codes (https://www.iso.org/obp/ui/#search/code/)	Manual entry Manual entry
A1.5.1	Institution full address	Full address where the organisation head office or coordinating centre is located.	Free text	Manual entry
A1.6	Institution website	If applicable, a dedicated website for the organisation can be entered.	URL	Manual entry
A1.7	Institution email contact	Contact email address for person responsible for institution entry in catalogue.	Free text; must take form "prefix@domain"	Manual entry
A1.8	Institution role	Roles of the institution in connection with data sources and data banks in the catalogue. Select one or more of the following:	Data originator/research/surveillance/other	Manual entry
<b>A1.8.1</b> A1.9	Institution role, other Institution expertise	If other, description of the primary role.  Free text summary of experience and expertise. Could relate to 1 or more data sources in the catalogue.	Free text Free text	Manual entry Manual entry
A1.10	Institution networks	Is the institution a member of an existing research network or consortium? If so, provide a list of the names of the networks or consortia the institution participates in.	Should take values within E1.1. If required value is not present in E1.1, an entry must be made in table E1-Network-Overview	Manual entry
A1.11	Institution resources	Does the institution team responsible for working with data sources in the catalogue include members with any of the following expertise? Select all that apply.	Epidemiologist/pharmacoepidemiologist/statistician/clinician/clinical pharmacologist/pharmacist/geneticist/pharmacogeneticist/IT specialist/ethics expertise/legal expertise/regulatory expertise	Manual entry
A1.12	Medical specialty	Does the institution or member have a medical specialty in any of the following therapeutic/disease areas? Select all that apply.		Manual entry
A1.13 A1.14	Medical specialty, other Study design experience	If other, list any additional specialty therapeutic/disease areas. Does the institution or member have expertise using any of the following study designs? Select all that apply.	Free text Cohort study/case control/case only/drug utilisation/interventional trial/routinely collected data-based pragmatic trial/meta-analysis/other	Manual entry Manual entry
A1.15	Study design experience, other	If other, provide a description study design experience.	Free text	Manual entry

EU = European Union; ID = identifier.

#### Metadata category: Institution - data sources and data banks

\* This will contain information for each institution entered in the catalogue and each data source to which they can currently provide access.

\* Metadata on experience, subset, access level and access platform are recommended only at data source level, as these metadata at the data bank level would provide minimal additional information at substantial contributor effort

Var ID	Var name	Description	Standards	Entry
A1.1	Institution ID	A persistent identifier for an institution. This may be created by the catalogue maintainer on first entry of an institution. It provides links across tables.		
A2.1	Experience with data sources	With which of the following data sources present in the catalogue does the institution have experience or expertise? Select one or more data sources from the list	Should take values within B1.1.	Manual entry
A2.1.1	Experience with data banks	With which of the following data banks present in the catalogue does the institution have experience or expertise? Select one or more data banks from the list	Should take values within C1.1.	Manual entry
A2.2	Is DAP	Does the institution have permission to access (an extract of) one or more data sources or data banks in the catalogue for research purposes?	No/yes	Manual entry
A2.2.1	Data sources	Name of data sources that can currently be accessed.	Should take values within B1.1. If required value is not present in B1.1, an entry must be made in table B1-Data source-Underlying population	Manual entry
A2.2.2	Data banks	Name of data banks that can currently be accessed.	Should take values within C1.1. If required value is not present in C1.1, an entry must be made in table C1-Data bank-Underlying population	Manual entry
A2.2.3	Data source population subset	Can the institution access the full data source or a subset?	Full/subset	A separate entry is made manually for each data source
A2.2.4	Data source population subset specification	If the institution can only access a subset, which subsets can it access? Select all that apply.	Preterm new-borns/term new-borns (0-27 days)/infants and toddlers (28 days - 23 months)/children (2-11 years)/adolescents (12-17 years)/adults (18-74 years)/adults (75 years and over)/pregnant women/renal impaired/hepatic impaired/immunocompromised/other	A separate entry is made manually for each data source
A2.2.5	Data source subset other	If 'other' is selected above, describe the subset that can be accessed.	Free text	A separate entry is made manually for each data source
A2.2.6	Data access level	Can the institution access individual level data or only aggregate level data (where individual level data refer to individual records and aggregate level data refer to summary tables)?	Individual/aggregate	A separate entry is made manually for each data source
A2.2.7	Data access extract	Can the institution access the whole data source or only an extract of the data source?	Whole/extract	A separate entry is made manually for each data source
A2.2.8	Data access platform	Can the institution access (an extract of) the data source on their local systems, or is access via a remote access system?	Local/remote	A separate entry is made manually for each data source
A2.2.9	Data access platform details	If data can only be accessed via a remote access system, describe the system and/or software used to access/process data.	Free text	A separate entry is made manually for each data source
A2.2.10	Data security	Describe the data encryption and security protections for the data source that are put in place by the DAP	Free text	A separate entry is made manually for each data source

DAP = data access provider; EU = European Union; ID = identifier.

# Metadata category: Institution - access contracts

<sup>\*</sup>To be populated if Ins-data sources-is DAP = yes

\* Metadata on DAP data access are recommended only at data source level, as these metadata at the data bank level would provide minimal additional information at substantial contributor effort

Var ID	Var name	Description	Standards	Entry
A1.1	Institution ID	A persistent identifier for an institution. This may be created by the catalogue maintainer on first entry of an institution. It provides links across tables.		
B1.1	Data source ID	A persistent identifier for a data source. This may be created by the catalogue maintainer on first entry of an institution. It provides links across tables.		
A3.1	Reason for access	What is the reason for being able to access (an extract of) the data source? Select one or more from the following:	Originator/research/surveillance/other	A separate entry is made manually for each data source selected in A2.3.1
A3.1.1	Description of other access	If other, provide a short description.	Free text	A separate entry is made manually for each data source selected in A2.3.1
A3.2	Access permission	Is permission required for your institute to access data source (e.g., from a data controller)?	no/always/study-dependent	A separate entry is made manually for each data source selected in A2.3.1
A3.3	Access agreement termination	The date of termination of the access agreement, if any.	DDMMYYYY	A separate entry is made manually for each data source selected in A2.3.1
A3.4	Access process	If permission to access data source is required, what is the process for obtaining access for a study?	Free text/URL	A separate entry is made manually for each data source selected in A2.3.1
A3.5	Access process time	On average, how long does it take for approval/access to be obtained following an application for data access?	Unit: day	A separate entry is made manually for each data source selected in A2.3.1
A3.6	Access fees	Are there fees for data access?	No/yes	A separate entry is made manually for each data source selected in A2.3.1

# Metadata category: Institution - studies

\*This table is created and automatically updated for institutions when there is an entry for the institution in Study-institutions

Var ID	Var name	Description	Standards	Entry
A1.1	Institution ID	A persistent identifier for an institution. This may be created by the catalogue maintainer on first entry of an institution. It provides links across tables.		
A4.1	Institution studies	A list of IDs of studies that have been conducted by the institution that are recorded in the catalogue	Should take values within F1.1.	This will be automatically populated via the link between Institution-studies and Study-institutions, by linking the Institution ID and Study ID.

EU = European Union; ID = identifier.

### Metadata category: Data source - underlying population

Var ID	Var name	Description	Standards	Entry
31.1	Data source ID	A persistent identifier for a data source. This may be created by the catalogue maintainer on first entry of a data source. It provides links across tables.		
B1.2	Data source name	Name of data source used in European projects	Free text	Manual entry
B1.2.1	Data source local name	If different from above, name of data source in the national language of the data source	Free text	Manual entry
B1.3	Data source acronym	Official acronym of the institution, if applicable.	Free text	Manual entry
B1.4	Data source type	Type of data source. Select one or more of the following:	Biobank/administrative claims/electronic health record/registry/other	Manual entry
B1.4.1	Data source type, other	If other, describe the type of data source.	Free text	Manual entry
B1.5	Description of underlying population	Summary description of the data source population (maximum 100 words) or URL to description	Free text/URL	Manual entry
B1.6	Data source countries	Countries where data originate (1 or more)	Select from list of countries, links to ISO 3166-1 country codes (https://www.iso.org/obp/ui/#search/code/)	Manual entry; may be automatically populated with entries in C1.5 when data bank entries are made
B1.6.1	Data source regions	Geographical regions that data source covers	Select from list of regions, links to ISO 3166-2 region codes (https://www.iso.org/obp/ui/#search/code/)	Manual entry; may be automatically populated with entries in C1.5.1 when data bank entries are made
B1.7	Care setting	Type of care setting(s) covered by data source.	General population/primary care/secondary care/tertiary care/other	Manual entry or may be automatically populated when C1.14 is populated for data banks in B4.1
B1.7.1	Care setting, other	If 'other,' description of the setting of care.	Free text	Manual entry or may be automatically populated when C1.14.1 is populated for data banks in B4.1
B.1.8	Data bank population overlap	Describe in text the overlap between the underlying populations of data banks within the data source.	Free text	Manual entry; left blank for data sources with only one data bank

Metadata category: Data source - access
Discrepancies between Data source - access and Data bank - access have been verified. Where there are differences are recommended, these are explained with a comment

Var ID	Var name	Description	Standards	Entry
B1.1	Data source ID	A persistent identifier for a data source. This may be created by the catalogue maintainer on first entry of a data source. It provides links across tables.		
B2.1	DAPs	List of DAPs that are listed in the catalogue as having (conditional) permission to access (an extract of) the data source	Should take values from A1.1	Automatically populated when a contributor enters A2.3 Ins-data sources-Is DAP as yes and a data source with corresponding Data source ID is selected
B2.2	Governance details	If available, provide documents or webpages that describe the overall governance of the data source (governing data access or utilisation for research purposes by existing DAPs)	Link to documents/URL	Manual entry
B2.2.1	Committee data access	Is there a committee that determines access to the data source by the DAPs that are already listed?	No/yes	Manual entry
B2.3	Policy data access	If available, provide documents or webpages that describe the policy for access to the data source.	Link to documents/URL	Manual entry. If data source consists of a single data bank, this may be automatically populated when C2.4 is populated
B2.4	Informed consent	Is informed consent required for use of the data for research purposes?	Required for general use/required for all studies/required for intervention studies/waiver/other	Manual entry. If data source consists of a single data bank, this may be automatically populated when C2.4 is populated
B2.4.1	Informed consent other	If other, describe the conditions when informed consent is required.	Free text	Manual entry. If data source consists of a single data bank, this may be automatically populated when C2.4.1 is populated
B2.5	Access to identifiable data	Can identifiable data be accessed in the data source by the DAPs that are already listed as having access (for example, patient name/practitioner name/practice name)?	No/yes	Manual entry. If data source consists of a single data bank, this may be automatically populated when C2.5 is populated
B2.5.1	Route to access to identifiable data	e If yes above, what is the route to access or process this information? What permission is required?	Free text	Manual entry. If data source consists of a single data bank, this may be automatically populated when C2.5.1 is populated
B2.6	Access to subject details	Can individual patients/practitioners/practices be contacted in the data source by the DAPs that are already listed?	No/yes	Manual entry. If data source consists of a single data bank, this may be automatically populated when C2.6 is populated
B2.6.1	Route to access to subject details	If yes above, what is the route to access this information? What permission is required?	Free text	Manual entry. If data source consists of a single data bank, this may be automatically populated when C2.6.1 is populated
B2.7	Audit possibility	Are external parties allowed to audit the data? For example, is it possible for an external party to audit the quality or validity of the data source?	No/yes	Manual entry
B2.8	Approval for publication	Is an approval needed for a DAP to publish the results of a study using the data source?	No/yes	Manual entry

EEA = European Economic Area ; EU = European Union; ID = identifier.

# Metadata category: Data source - qualification

Var ID	Var name	Description	Standards	Entry
B1.1	Data source ID	A persistent identifier for a data source. This may be created by the catalogue maintainer on first entry of a data source. It provides links across tables.		
B3.1	Data source qualification	Has the data source successfully undergone a qualification process (e.g., from the EMA)?	No/yes	Manual entry
B3.1.1	Description of qualifications	If yes, describe the qualification(s) granted.	Free text	Manual entry

EMA = European Medicines Agency; ID = identifier.

B1.1	Var name Data source ID	Description  A persistent identifier for a data source. This may be created by the catalogue maintainer on first entry of a data source. It provides links	Standards	Entry
B4.1	Data banks	catalogue maintainer on first entry of a data source. It provides links across tables.  A list of the data banks that might be included in this data source	Takes values from C1.1	Manual entry; selected from a list of data
34.2	Data bank families	A list of the families of data banks included in the data source	Hospital discharge records/primary care medical records/pharmacy	names (C1.2) linked to identifier C1.1  Manual entry or automatically populated v
			dispensation records/birth registry/induced terminations registry/congenital anomaly registry/inhabitant registry/registration with healthcare system/outpatient visit records/emergency care	data banks are entered in B4.1 with values C5.1
			discharge records/exemptions from co-payment/diagnostic tests or procedures reimbursement/death registry/cancer registry/other disease registry/vaccine registry/biobank/administrative	
. 2 4	Data hank familias ather	If lether explanted above decaribe the type of data book	claims/spontaneous reporting of adverse drug reactions	Manual antry or automatically populated
l.2.1	Data bank families, other	If 'other' selected above, describe the type of data bank.	Free text	Manual entry or automatically populated v data banks are entered in B4.1 with value C5.1.1
l.3	Geographic regions	Are data on geographic region available?	No/yes	Manual entry or automatically populated vidata banks are entered in B4.1 with value C6
1.4	Family linkage	Is any linkage available in the data bank between any of the following persons?	Household/mother-child/father-child/sibling	Manual entry or automatically populated data banks are entered in B4.1 with value C6
.4.1	Family linkage routine	Is familial linkage created routinely or can linkage be performed on an ad-hoc basis?	Routine/ad hoc	Manual entry or automatically populated data banks are entered in B4.1 with value
1.4.2	Family linkage availability	Is familial linkage available for all of the data source population or a subset of individuals (or records)?	Full/subset	C6 Manual entry or automatically populated data banks are entered in B4.1 with value
1.4.3	Family linkage availability details	If a familial linkage is available for a subset of individuals (or records) only, provide a short description of the subset.	Free text	C6 Manual entry or automatically populated data banks are entered in B4.1 with value
4.5	Sociodemographics included	Which of the following sociodemographic information is included?	None/age/sex/gender/ethnicity/country of origin/socioeconomic	C6 Manual entry or automatically populated data banks are entered in B4.1 with value
		Select all that apply.	status/marital status/education level/type of residency/living in rural area/health area/deprivation index/pharmaceutical co-payment/other	C6
4.6	Lifestyle factors included	Which of the following lifestyle information is included? Select all that apply.	None/tobacco use/alcohol use/frequency of exercise/other	Manual entry or automatically populated data banks are entered in B4.1 with value C6
4.7	Diagnosis codes included	Are diagnostic codes included?	No/yes	Manual entry or automatically populated data banks are entered in B4.1 with value C6
4.7.1	Diagnosis code vocabulary	If yes, what vocabulary is used? Select from the following:	ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other	Manual entry or automatically populated data banks are entered in B4.1 with value
4.7.2	Diagnosis code not coded	If Not coded (Free text), approximately what percentage of records are not coded?	Unit: %, not applicable	C6 Manual entry
4.7.3	Diagnosis, other	Is other information on diagnoses of patient outcomes recorded, not in the form of diagnostic codes?	Free text	Manual entry or automatically populated data banks are entered in B4.1 with value C6
4.8	Hospital admission discharge	Is information on hospital admission and/or hospital discharge available?	No/yes	Manual entry or automatically populated data banks are entered in B4.1 with value C6
4.8.1	ICU admission	Is information on intensive care unit admission available?	No/yes	Manual entry or automatically populated data banks are entered in B4.1 with value
4.9	Cause of death	Is cause of death available?	No/yes	C6 Manual entry or automatically populated data banks are entered in B4.1 with value
4.9.1	Cause of death vocabulary	If yes, what vocabulary is used? Select from the following:	ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other	C6 Manual entry or automatically populated data banks are entered in B4.1 with value
4.9.2	Cause of death not coded	If Not coded (Free text), approximately what percentage of records	Unit: %, not applicable	data banks are entered in B4.1 with value C6  Manual entry
4.9.3	Cause of death code, other	are not coded?  If 'other,' what vocabulary is used?	Free text	Manual entry or automatically populated data banks are entered in B4.1 with value
4.10	Rare diseases	Are rare diseases (<1 in 2000 people) captured?	No/yes	C6 Manual entry or automatically populated data banks are entered in B4.1 with value
4.11	Prescriptions included	Is information on prescription of medications included?	No/yes	C6 Manual entry or automatically populated
4.11.1	Prescriptions vocabulary	If yes, what vocabulary is used? Select from the following:	ATC/RxNorm/EphMRA/ALT/DrugBank/Not coded (Free text)/Other	data banks are entered in B4.1 with value C6  Manual entry or automatically populated
4.11.2	Prescriptions not coded	If Not coded (Free text), approximately what percentage of records	Unit: %, not applicable	data banks are entered in B4.1 with value C6 Manual entry
4.11.3	Prescriptions vocabulary, other	are not coded?  If 'other,' what vocabulary is used?	Free text	Manual entry or automatically populated data banks are entered in B4.1 with value
4.12	Dispensings included	Is information on dispensing of medications included?	No/yes	C6 Manual entry or automatically populated
4.12.1	Dispensings vocabulary	If yes, what vocabulary is used? Select from the following:	ATC/RxNorm/EphMRA/ALT/DrugBank/Not coded (Free text)/Other	data banks are entered in B4.1 with value C6 Manual entry or automatically populated
4.12.2	Dispensings not coded	If Not coded (Free text), approximately what percentage of records	Unit: %, not applicable	data banks are entered in B4.1 with value C6 Manual entry
4.12.3	Dispensings vocabulary, other	are not coded?  If 'other,' what vocabulary is used?	Free text	Manual entry or automatically populated data banks are entered in B4.1 with value
4.13	Product information	Is product information available? Select all items that apply.	Brand name/batch number/formulation/strength/package size	C6 Manual entry or automatically populated
4.13.1	Product information, product	If product information is included, what vocabulary is used to describe	e ART 57/IFA GmbH/EQDM/SPN/MTHSPL/Not coded (Free	data banks are entered in B4.1 with value C6 Manual entry or automatically populated
4.13.2	vocabulary  Product vocabulary, other	the product?  If 'other,' what vocabulary is used?	text)/Other Free text	data banks are entered in B4.1 with value C6 Manual entry or automatically populated
	·	·		data banks are entered in B4.1 with value C6
4.13.3	Product information, substance vocabulary	If substance information is included, what vocabulary is used to describe the substance?	ART 57/IFA GmbH/EQDM/SPN/MTHSPL/Not coded (Free text)/Other	Manual entry or automatically populated data banks are entered in B4.1 with value C6
4.13.4	Substance vocabulary, other	If 'other,' what vocabulary is used?	Free text	Manual entry or automatically populated data banks are entered in B4.1 with value C6
4.13.5	Other medicines information	Is other information on medicines or products included?	No/yes	Manual entry or automatically populated data banks are entered in B4.1 with value C6
4.13.6	Other medicines information details	If yes to the above, select all the items that apply.	Dose/dosage regime/route of administration/product information	Manual entry or automatically populated data banks are entered in B4.1 with value
4.14	ATMP	Is information on advanced therapy medicinal products included?	No/yes	C6 Manual entry or automatically populated data banks are entered in B4.1 with value
4.15	Contraception	Is information on contraceptives included?	No/yes	C6 Manual entry or automatically populated data banks are entered in B4.1 with value
4.15.1				C6
	Emergency contraception	If yes, is information on emergency contraceptives included?	No/yes	Manual entry or automatically populated
4.16	Emergency contraception  Indication for use	If medicines information is captured, is the indication for use	No/yes/not applicable	Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated
				Manual entry or automatically populated vidata banks are entered in B4.1 with value C6 Manual entry or automatically populated vidata banks are entered in B4.1 with value C6
4.16.1	Indication for use Indication vocabulary	If medicines information is captured, is the indication for use recorded?  If yes, what vocabulary is used? Select from the following:	No/yes/not applicable  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED  CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other	Manual entry or automatically populated vidata banks are entered in B4.1 with value C6 Manual entry or automatically populated vidata banks are entered in B4.1 with value C6 Manual entry or automatically populated vidata banks are entered in B4.1 with value C6
4.16.1 4.16.2	Indication for use	If medicines information is captured, is the indication for use recorded?	No/yes/not applicable  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED	Manual entry or automatically populated vidata banks are entered in B4.1 with value C6  Manual entry or automatically populated vidata banks are entered in B4.1 with value C6  Manual entry or automatically populated vidata banks are entered in B4.1 with value C6  Manual entry or automatically populated vidata banks are entered in B4.1 with value C6  Manual entry
4.16.1 4.16.2 4.16.3	Indication for use Indication vocabulary Indication not coded Indication vocabulary, other	If medicines information is captured, is the indication for use recorded?  If yes, what vocabulary is used? Select from the following:  If Not coded (Free text), approximately what percentage of records are not coded?	No/yes/not applicable  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED  CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable	Manual entry or automatically populated of data banks are entered in B4.1 with value C6  Manual entry or automatically populated of data banks are entered in B4.1 with value C6  Manual entry or automatically populated of data banks are entered in B4.1 with value C6  Manual entry  Manual entry  Manual entry or automatically populated of data banks are entered in B4.1 with value C6  Manual entry or automatically populated of data banks are entered in B4.1 with value C6  Manual entry or automatically populated of data banks are entered in B4.1 with value C6
4.16.1 4.16.2 4.16.3 <b>4.17</b>	Indication for use Indication vocabulary Indication not coded Indication vocabulary, other Administration vaccines include	If medicines information is captured, is the indication for use recorded?  If yes, what vocabulary is used? Select from the following:  If Not coded (Free text), approximately what percentage of records are not coded?  If 'other,' what vocabulary is used?  Is information on the administration of vaccines included?	No/yes/not applicable  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable  Free text  No/yes	Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry  Manual entry  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6
4.16.1 4.16.2 4.16.3 4.17	Indication for use Indication vocabulary Indication not coded Indication vocabulary, other Administration vaccines include Administration other injectable medicines	If medicines information is captured, is the indication for use recorded?  If yes, what vocabulary is used? Select from the following:  If Not coded (Free text), approximately what percentage of records are not coded?  If 'other,' what vocabulary is used?  Is information on the administration of vaccines included?  Is information on the administration of other injectable medicines included?	No/yes/not applicable  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED  CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable  Free text  No/yes  No/yes	Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry  Manual entry  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6
4.16.1 4.16.2 4.16.3 4.17 4.17.1	Indication for use Indication vocabulary Indication not coded Indication vocabulary, other Administration vaccines include Administration other injectable medicines Medical devices	If medicines information is captured, is the indication for use recorded?  If yes, what vocabulary is used? Select from the following:  If Not coded (Free text), approximately what percentage of records are not coded?  If 'other,' what vocabulary is used?  Is information on the administration of vaccines included?  Is information on the administration of other injectable medicines included?  Is information on medical devices included?	No/yes/not applicable  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable  Free text  No/yes  No/yes	Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6
4.16.1 4.16.2 4.16.3 4.17 4.17.1 4.18 4.19	Indication for use Indication vocabulary Indication not coded Indication vocabulary, other Administration vaccines include Administration other injectable medicines Medical devices Procedures included	If medicines information is captured, is the indication for use recorded?  If yes, what vocabulary is used? Select from the following:  If Not coded (Free text), approximately what percentage of records are not coded?  If 'other,' what vocabulary is used?  Is information on the administration of vaccines included?  Is information on medical devices included?  Is information on medical devices included?  Is information on procedures (e.g., diagnostic tests, therapeutic, surgical) included?	No/yes/not applicable  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable  Free text  No/yes  No/yes  No/yes	Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry  Manual entry  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6
4.16.1 4.16.2 4.16.3 4.17 4.17.1 4.18	Indication for use Indication vocabulary Indication not coded Indication vocabulary, other Administration vaccines include Administration other injectable medicines Medical devices	If medicines information is captured, is the indication for use recorded?  If yes, what vocabulary is used? Select from the following:  If Not coded (Free text), approximately what percentage of records are not coded?  If 'other,' what vocabulary is used?  Is information on the administration of vaccines included?  Is information on medical devices included?  Is information on medical devices included?	No/yes/not applicable  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable  Free text  No/yes  No/yes	Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry  Manual entry  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6
4.16.1 4.16.2 4.16.3 4.17 4.17.1 4.18 4.19 4.19.1	Indication for use Indication vocabulary Indication not coded Indication vocabulary, other  Administration vaccines include Administration other injectable medicines Medical devices  Procedures included  Procedures vocabulary  Procedures not coded	If medicines information is captured, is the indication for use recorded?  If yes, what vocabulary is used? Select from the following:  If Not coded (Free text), approximately what percentage of records are not coded?  If 'other,' what vocabulary is used?  Is information on the administration of vaccines included?  Is information on medical devices included?  Is information on medical devices included?  Is information on procedures (e.g., diagnostic tests, therapeutic, surgical) included?  If yes, what vocabulary is used? Select from the following:  If Not coded (Free text), approximately what percentage of records are not coded?	No/yes/not applicable  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable  Free text  No/yes  No/yes  No/yes  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable	Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry
4.16.1 4.16.2 4.16.3 4.17 4.17.1 4.18 4.19 4.19.1 4.19.2 4.19.3	Indication for use Indication vocabulary Indication not coded Indication vocabulary, other  Administration vaccines include Administration other injectable medicines Medical devices  Procedures included  Procedures vocabulary  Procedures not coded  Procedure vocabulary, other	If medicines information is captured, is the indication for use recorded?  If yes, what vocabulary is used? Select from the following:  If Not coded (Free text), approximately what percentage of records are not coded?  If 'other,' what vocabulary is used?  Is information on the administration of vaccines included?  Is information on medical devices included?  Is information on procedures (e.g., diagnostic tests, therapeutic, surgical) included?  If yes, what vocabulary is used? Select from the following:  If Not coded (Free text), approximately what percentage of records are not coded?  If 'other,' what vocabulary is used?	No/yes/not applicable  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable  Free text  No/yes  No/yes  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable  Free text	Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry  Manual entry  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6
4.16.1 4.16.2 4.16.3 4.17 4.17.1 4.18 4.19 4.19.1 4.19.2 4.19.3 4.19.4	Indication for use Indication vocabulary Indication not coded Indication vocabulary, other  Administration vaccines include Administration other injectable medicines Medical devices  Procedures included  Procedures vocabulary  Procedure vocabulary, other  Procedure results	If medicines information is captured, is the indication for use recorded?  If yes, what vocabulary is used? Select from the following:  If Not coded (Free text), approximately what percentage of records are not coded?  If 'other,' what vocabulary is used?  Is information on the administration of vaccines included?  Is information on medical devices included?  Is information on procedures (e.g., diagnostic tests, therapeutic, surgical) included?  If yes, what vocabulary is used? Select from the following:  If Not coded (Free text), approximately what percentage of records are not coded?  If 'other,' what vocabulary is used?  Are results of procedures available?	No/yes/not applicable  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable  Free text  No/yes  No/yes  No/yes  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable  Free text  No/yes	Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6
4.16.1 4.16.2 4.16.3 4.17 4.17.1 4.18 4.19 4.19.1 4.19.2 4.19.3 4.19.4	Indication for use Indication vocabulary Indication not coded Indication vocabulary, other  Administration vaccines include Administration other injectable medicines Medical devices  Procedures included  Procedures vocabulary  Procedures not coded  Procedure vocabulary, other	If medicines information is captured, is the indication for use recorded?  If yes, what vocabulary is used? Select from the following:  If Not coded (Free text), approximately what percentage of records are not coded?  If 'other,' what vocabulary is used?  Is information on the administration of vaccines included?  Is information on medical devices included?  Is information on procedures (e.g., diagnostic tests, therapeutic, surgical) included?  If yes, what vocabulary is used? Select from the following:  If Not coded (Free text), approximately what percentage of records are not coded?  If 'other,' what vocabulary is used?	No/yes/not applicable  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable  Free text  No/yes  No/yes  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable  Free text	Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6  Manual entry or automatically populated data banks are entered in B4.1 with value C6
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Is information on medical devices included?  Is information on procedures (e.g., diagnostic tests, therapeutic, surgical) included?  If yes, what vocabulary is used? Select from the following:  If Not coded (Free text), approximately what percentage of records are not coded?  If other, what vocabulary is used?  Are results of procedures available?  If yes, what vocabulary is used? Select from the following:  If Not coded (Free text), approximately what percentage of records are not coded?  If other, what vocabulary is used? Select from the following:  If Not coded (Free text), approximately what percentage of records are not coded?  If other, what vocabulary is used?  Is information on clinical measures included (e.g., BMI, blood pressure)?  Is information on the healthcare centre (e.g., pharmacy, general practice, hospital) available?  Is information on the person providing healthcare (e.g., physician, pharmacist, specialist) available?  Is genotyping information available?  If yes, what vocabulary is used? Select from the following:  If other, what vocabulary is used? Select from the following:  If other, what vocabulary is used? Select from the following:  If other, what vocabulary is used?  A short summary of how genetic information is captured in the data source.  Is biomarker information available?	No/yes/not applicable  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other Unit: %, not applicable Free text  No/yes  No/yes  No/yes  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other Unit: %, not applicable Free text  No/yes  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other Unit: %, not applicable Free text  No/yes  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other Unit: %, not applicable Free text  No/yes  No/yes  No/yes  OGG/FG/GO/EGO/SOPHARM/PHARE/other  Free text  Free text  No/yes	Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry  Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with v
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A short summary of how patient-generated information (e.g., from	No/yes/not applicable  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED  CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable  Free text  No/yes  No/yes  No/yes  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED  CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable  Free text  No/yes  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED  CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable  Free text  No/yes  No/yes  No/yes  No/yes  No/yes  OGG/FG/GO/EGO/SOPHARM/PHARE/other  Free text  Free text  No/yes  BMO/SMASH/FOB/Jother  Free text  Free text  Free text  No/yes  Profe text  No/yes  Profe text  Free text  No/yes  Free text  No/yes  Free text  No/yes	Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual
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No/yes/not applicable  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED  CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable  Free text  No/yes  No/yes  No/yes  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED  CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable  Free text  No/yes  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED  CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable  Free text  No/yes  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED  CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable  Free text  No/yes  No/yes  No/yes  No/yes  OGG/FG/GO/EGO/SOPHARM/PHARE/other  Free text  Free text	Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual
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No/yes/not applicable  ICPC/ICD8/ICD10/ICD1/Read/ SNOMED/SNOMED  CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable  Free text  No/yes  No/yes  No/yes  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED  CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable  Free text  No/yes  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED  CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable  Free text  No/yes  No/yes  No/yes  No/yes  OGG/FG/GO/EGO/SOPHARM/PHARE/other  Free text  Free text  No/yes  BMO/SMASH/FOBI/other  Free text  Free text  Free text  No/yes  Free text  No/yes  Free text  AQGL-8D/QOLS/MQQL/MQQL-E/HRQQL/WHOQQL/EQSD/15D/SF-3B/HUl/Vother	Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual
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Select from the following:  If Not coded (Free text), approximately what percentage of records are not coded?  If 'other,' what vocabulary is used?  Is information on the administration of vaccines included?  Is information on medical devices included?  Is information on procedures (e.g., diagnostic tests, therapeutic, surgical) included?  If yes, what vocabulary is used? Select from the following:  If Not coded (Free text), approximately what percentage of records are not coded?  If 'other,' what vocabulary is used?  Are results of procedures available?  If yes, what vocabulary is used? Select from the following:  If Not coded (Free text), approximately what percentage of records are not coded?  If 'other,' what vocabulary is used?  If 'other,' what vocabulary is used?  Is information on clinical measures included (e.g., BMI, blood pressure)?  Is information on the healthcare centre (e.g., pharmacy, general practice, hospital) available?  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No/yes/not applicable  ICPC/ICD9/ICD10/ICD1//Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable Free text  No/yes  No/yes  No/yes  No/yes  ICPC/ICD9/ICD10/ICD1//Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable Free text  No/yes  ICPC/ICD9/ICD10/ICD1//Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable Free text  No/yes  ICPC/ICD9/ICD10/ICD1//Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable Free text  No/yes  No/yes  No/yes  No/yes  No/yes  OGG/FG/GO/EGO/SOPHARM/PHARE/other  Free text  Free text  Free text  No/yes  BMO/SMASH/FOBI/other  Free text  AQUI-8D/QOLS/MQOL/MQOL-E/HRQOL/WHOQOL/EQSD/15D/SF-3G/SF-6D/HU/Jother  Free text  No/yes	Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual
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Select from the following:  If Not coded (Free text), approximately what percentage of records are not coded?  If other, what vocabulary is used?  Is information on the administration of vaccines included?  Is information on the administration of other injectable medicines included?  Is information on procedures (e.g., diagnostic tests, therapeutic, surgical) included?  If yes, what vocabulary is used? Select from the following:  If Not coded (Free text), approximately what percentage of records are not coded?  If yes, what vocabulary is used?  Are results of procedures available?  If yes, what vocabulary is used? Select from the following:  If Not coded (Free text), approximately what percentage of records are not coded?  If other, what vocabulary is used?  Is information on clinical measures included (e.g., BMI, blood pressure)?  Is information on the healthcare centre (e.g., pharmacy, general practice, hospital) available?  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No/yes/not applicable  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CTMedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable Free text  No/yes  No/yes  No/yes  No/yes  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable Free text  No/yes  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable Free text  No/yes  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable Free text  No/yes  No/yes  No/yes  No/yes  No/yes  SOG/FG/GO/EGO/SOPHARM/PHARE/other Free text  Free text  Free text  Free text  Free text  Free text  ACOL-8D/QOLS/MQOL/MQOL-E/HRQOL/WHOQOL/EQSD/15D/SF-36/SF-6D/HUlrother Free text  No/yes  No/yes	Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual
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Select from the following:  If Not coded (Free text), approximately what percentage of records are not coded?  If other, what vocabulary is used?  Is information on the administration of vaccines included?  Is information on the administration of other injectable medicines included?  Is information on procedures (e.g., diagnostic tests, therapeutic, surgical) included?  If yes, what vocabulary is used? Select from the following:  If Not coded (Free text), approximately what percentage of records are not coded?  If Not coded (Free text), approximately what percentage of records are not coded?  If Not coded (Free text), approximately what percentage of records are not coded?  If Not coded (Free text), approximately what percentage of records are not coded?  If Not coded (Free text), approximately what percentage of records are not coded?  If vother, what vocabulary is used?  Is information on clinical measures included (e.g., BMI, blood pressure)?  Is information on the healthcare centre (e.g., pharmacy, general practice, hospital) available?  Is genotyping information available?  If yes, what vocabulary is used? Select from the following:  If 'other,' what vocabulary is used?  A short summary of how genetic information is captured in the data source.  Is patient-generated information (e.g., from wearable devices) available?  If yes, what vocabulary is used? Select from the following:  If 'other,' what vocabulary is used?  A short summary of how patient-generated information (e.g., from wearable devices) available?  A short summary of how patient-generated information (e.g., from wearable devices) is captured in the data source.  Is patient-generated information (e.g., from wearable devices) available?  A short summary of how patient-generated information (e.g., from wearable devices) is captured in the data source.  Are quality of life measures available? Select all that apply.  If other, specify additiona	Nolyes/not applicable  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CTMedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable Free text  Nolyes  Nolyes  Nolyes  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable Free text  Nolyes  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable Free text  Nolyes  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable Free text  Nolyes  Nolyes  Nolyes  Nolyes  Nolyes  SGG/FG/GO/EGO/SOPHARM/PHARE/other Free text  Free text  Free text  Free text  Nolyes  BMO/SMASH/FOB/Jother Free text  AQOL-8D/QOLS/MQOL/MQOL-E/HRQOL/WHOQOL/EQSD/15D/SF-SG/SF-ED/HUI/other Free text  Nolyes  Nolyes  Nolyes  Nolyes  Nolyes	Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual
4.16.1 4.16.1 4.16.2 4.16.3 4.17.1 4.18.4 4.19.1 4.19.1 4.19.1 4.19.5 4.19.6 4.19.7 4.19.7 4.20 4.21 4.22.1 4.22.1 4.23.3 4.24 4.23.1 4.24.1 4.25 4.23.3 4.24 4.23.1 4.23.2	Indication for use Indication vocabulary Indication not coded Indication vocabulary, other  Administration vaccines included Administration other injectable medicines Medical devices  Procedures included  Procedures vocabulary  Procedure results  Procedure results vocabulary  Procedure results vocabulary  Procedure results vocabulary  Clinical measures included  Healthcare centre  Healthcare provider  Genetic data vocabulary, other  Genetic data vocabulary  Biomarker data  Biomarker data vocabulary  Biomarker data vocabulary  Patient-generated data  Patient-generated data summary  Quality of life, other  Costs  Free text	If medicines information is captured, is the indication for use recorded?  If yes, what vocabulary is used? Select from the following:  If Not coded (Free text), approximately what percentage of records are not coded?  If other, what vocabulary is used?  Is information on the administration of vaccines included?  Is information on the administration of other injectable medicines included?  Is information on procedures (e.g., diagnostic tests, therapeutic, surgical) included?  If yes, what vocabulary is used? Select from the following:  If Not coded (Free text), approximately what percentage of records are not coded?  If 'other,' what vocabulary is used?  Are results of procedures available?  If yes, what vocabulary is used? Select from the following:  If Not coded (Free text), approximately what percentage of records are not coded?  If 'other,' what vocabulary is used?  If Not coded (Free text), approximately what percentage of records are not coded?  If other,' what vocabulary is used?  Is information on clinical measures included (e.g., BMI, blood pressure)?  Is information on the healthcare centre (e.g., pharmacy, general practice, hospital) available?  Is information on the person providing healthcare (e.g., physician, pharmacist, specialist) available?  If yes, what vocabulary is used? Select from the following:  If 'other,' what vocabulary is used?  A short summary of how genetic information is captured in the data source.  Is biomarker information available?  If yes, what vocabulary is used? Select from the following:  If 'other,' what vocabulary is used?  A short summary of how patient-generated information (e.g., from wearable devices) available?  A short summary of how patient-generated information (e.g., from wearable devices) is captured in the data source.  Is patient-generated information (e.g., from wearable devices) is captured in the data source.  Are quality of life measures available? Select all that apply.  If other, specify additional quality of life measures.  Is information on costs of he	No/yes/not applicable  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CTMedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable Free text  No/yes  No/yes  No/yes  No/yes  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable Free text  No/yes  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable Free text  No/yes  ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other  Unit: %, not applicable Free text  No/yes  No/yes  No/yes  No/yes  No/yes  SOG/FG/GO/EGO/SOPHARM/PHARE/other Free text  Free text  Free text  Free text  Free text  Free text  ACOL-8D/QOLS/MQOL/MQOL-E/HRQOL/WHOQOL/EQSD/15D/SF-36/SF-6D/HUlrother Free text  No/yes  No/yes	Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual entry or automatically populated data banks are entered in B4.1 with value C6 Manual

BMI = body mass index; ID = identifier; NLP = Natural language processing

.Classified as internal/staff contractors by the European Medicines Agency		

# Metadata category: Data source - data banks Unit of observation of this table is the pair Data source - Data bank

Var ID	Var name	Description	Standards	Entry
B1.1	Data source ID	A persistent identifier for a data source. This may be created by the catalogue maintainer on first entry of a data source. It provides links across tables.		
B4.1	Data bank ID	A list of the data banks that might be included in this data source	Takes values from C1.1	This is already entered in B4
B5.1	Linkage description	Provide a high-level description of the linkages that are currently available between data banks in the data source (max 100 words).	Free text	Manual entry
B5.2	Linkage strategy	The linkage method that was used to link data banks. One entry per data bank.	Deterministic/probabilistic/combination/other	Manual entry
B5.2.1	Linkage variable	If a single variable (or linkage key) is used to link a data bank to others, a name and description of the variable is provided. One entry per data bank.	Free text	Manual entry
B5.2.2	Linkage variable unique	If a single variable is used to link a data bank to others, is the variable a unique identifier? One entry per data bank.	No/yes	Manual entry
B5.3.1	Linkage completeness	Provide a high-level description of the completeness of linkages that are currently available between data banks in the data source (max 100 words).	Free text	Manual entry

If a data source has a well-defined poulation data bank, e.g. in nordic registries, the % of the population of each data bank that links to the population databank can be calculated

Metadata category: Data source - quantitative descriptors

\* The date of last update (entry) of quantitative descriptor variables will be automatically presented alongside each of these variables in the catalogue

Var ID	Var name	descriptor variables will be automatically presented alongside each of <b>Description</b>	Standards	Entry
B1.1	Data source ID	A persistent identifier for a data source. This may be created by the catalogue maintainer on first entry of a data source. It provides links across tables.		
B6.1	Population size	Total number of unique individuals with records captured in the data source (most recent count). In the catalogue, this will accommodate counts per year.	Numeric	Manual entry
B6.1.1	Population size active	Number of unique, active, or currently registered individuals with records captured in the data source (most recent count). In the catalogue, this will accommodate counts per year.	Numeric	Manual entry
B6.2	Number of individuals with biological samples	Number of unique individuals with records of biological samples (e.g., blood, urine) (most recent count). In the catalogue, this will accommodate counts per year.	Numeric	Manual entry
B6.3	Median observation time	Median time for which unique individuals with records captured in the data source are observable (most recent count).	Unit years	Manual entry; in future implementations scripts or functions could work together with a common data model to extract this information directly from a data source
B6.3.1		Median time for which unique, active, or currently registered individuals with records captured in the data source are observable (most recent count).	Unit: years	Manual entry; in future implementations scripts or functions could work together with a common data model to extract this information directly from a data source
B6.4	Population size by age	Total number of unique individuals with records captured in the data source (most recent count), stratified by age	Numeric, for each of the following categories: 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 75 years), adults (76 years and over)	Manual entry; in future implementations scripts or functions could work together with a common data model to extract this information directly from a data source
B6.4.1	Population size active by age	Number of unique, active, or currently registered individuals with records captured in the data source (most recent count), stratified by age	Numeric, for each of the following categories: 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 75 years), adults (76 years and over)	Manual entry; in future implementations scripts or functions could work together with a common data model to extract this information directly from a data source
B6.5	Median age of underlying population	Median age of the underlying population (e.g., in the geographical population that the data source covers, based on external estimates, e.g., census)	Numeric	Manual entry; in future implementations scripts or functions could work together with a common data model to extract this information directly from a data source
B6.5.1	Median age data source	Median age of individuals within data source	Numeric	Manual entry; in future implementations scripts or functions could work together with a common data model to extract this information directly from a data source
B6.6	Proportion female in the underlying population	Proportion of females in the underlying population (based on external estimates, e.g., census)	Unit: %	Manual entry; in future implementations scripts or functions could work together with a common data model to extract this information directly from a data source
B6.6.1	Proportion female data source	Proportion of females in the data source	Unit: %	Manual entry; in future implementations scripts or functions could work together with a common data model to extract this information directly from a data source
B6.7	Proportion ethnicity in the underlying population	Proportion of people per ethnicity in the underlying population (based on external estimates, e.g., census)	Unit: %, per ethnicity group	Manual entry; in future implementations scripts or functions could work together with a common data model to extract this information directly from a data source
B6.7.1	Proportion ethnicity data source	Proportion of people per ethnicity in the data source	Unit: %, per ethnicity group	Manual entry; in future implementations scripts or functions could work together with a common data model to extract this information directly from a data source

# Metadata category: Data source - ETL

Var ID	Var name	Description	Standards	Entry
B1.1	Data source ID	A persistent identifier for a data source. This may be created by the catalogue maintainer on first entry of a data source. It provides links across tables.		
B7.1	Data source ETL	Has the data source been ETL-d to a common data model?	No/yes	
B7.2	Data source ETL CDM	Name of CDM(s) to which the data source has been ETL-d	Should take values within D1.1	
B7.3	Data source ETL CDM version	Version(s) of CDM(s) to which the data source has been ETL-d	Free text	Manual entry; could automatically take values from F4.3 study-mappings
B7.4	Data source ETL specifications	If available, a list of ETL specification documents uploaded to the catalogue. These documents describe the mapping of the data source to the CDM.	URL/uploaded documents	Manual entry; could automatically take values from F4.4 study-mappings
B7.4.1	Data source ETL code	If available, the ETL code or scripts uploaded to the catalogue. These are the code or scripts that were used to transform data from the original source to the CDM.	URL/uploaded documents	Manual entry; could automatically take values from F4.4 study-mappings

CDM = common data model; ETL = extract, transform, load; ID = identifier.

# Metadata category: Data source - studies

\*This table is created and automatically updated for institutions when there is an entry for the institution in Study-data sources-data source name

Var ID	Var name	Description	Standards	Entry
B1.1	Data source ID	A persistent identifier for a data source. This may be created by the catalogue maintainer on first entry of a data source. It provides links across tables.		
B8.1	Data source studies	A list of IDs of studies that have been conducted using the data source that are recorded in the catalogue	Should take values in F1.1	Automatically populated when the data source ID is entered in F3.3 - Study - data sources and data banks
B8.2	Regulatory use	List the types of regulatory studies that the data source has been used for (e.g., PASS, PAES,).	Should take values in F2.4 - study - protocol	Automatically populated with values from F2.4 - Type of study, when studies are entered, and the data source ID is entered in F3.3.

### Metadata category: Data source - publications

Var ID	Var name	Description	Standards	Entry
B1.1	Data source ID	A persistent identifier for a data source. This may be created by the catalogue maintainer on first entry of a data source. It provides links across tables.		
B9.1	Data source website	If applicable, a dedicated website for the data source	URL	Manual entry
B9.2	Data source publications	A list of peer-reviewed papers describing the data source or its use for pharmacoepidemiologic research	Allow individual AMA format citations / URL to list of publications.	Automatically populated when an entry is made in F7.2-Study report, using the study IDs (F1.1) where the data source is selected in F3.3-Data sources and data banks
B9.3	Data source, other information	A list of URLs to other relevant resources describing the data source or its use in pharmacoepidemiologic studies	URL	Manual entry

AMA = American Medical Association; ID = identifier.

### Metadata category: Data bank - underlying population

Var ID	Var name	Description	Standards	Entry
C1.1		A persistent identifier for a data bank. This may be created by the catalogue maintainer on first entry of a data bank. It provides links across tables.		
C1.2	Data bank name	Name of data bank used in European projects	Free text	Manual entry
C1.2.1	Data bank local name	If different from above, name of data bank in the national language of the data source		Manual entry
C1.3	Data bank acronym	If applicable	Free text	Manual entry
C1.4	Description of underlying population	Provide a summary description of the underlying population (maximum 100 words) or URL to a description	Free text/URL	Manual entry
C1.5	Data bank countries	Countries where data originate (1 or more)	Select from list of countries, links to ISO 3166-1 country codes (https://www.iso.org/obp/ui/#search/code/)	Manual entry
C1.5.1	Data bank regions	Geographical regions that data bank covers	Select from list of regions, links to ISO 3166-2 region codes (https://www.iso.org/obp/ui/#search/code/)	Manual entry
C1.6	Causes of population entry	Select the possible causes for a person to enter the underlying population of the data bank.	Birth/immigration/residency obtained/insurance coverage start/disease diagnosis/treatment started/practice registration/other	Manual entry
C1.6.1	Causes of population entry other	If other, specify the causes of entry to the underlying population.	Free text	Manual entry
C1.7	Causes of population exit	Select the possible causes for a person to leave the underlying population of the data bank.	Death/emigration/insurance coverage end/practice deregistration/loss to follow up/other	Manual entry
C1.7.1		If other, specify the causes of exit from the underlying population.	Free text	Manual entry
C1.8		Which population age groups are captured in the data bank? Select all that are relevant.	Numeric, for each of the following categories: 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 75 years), adults (76 years and over)	Manual entry
C1.9		Does the data bank collect information on pregnant women and/or neonatal subpopulation?	No/yes	Manual entry
C1.10	Disease subpopulations	Does the data bank collect information on a specific disease subpopulation (e.g., as in a disease-specific registry)?	No/yes	Manual entry
C1.10.1		If yes, which disease subpopulations does the data bank collect information on?	Free text	Manual entry
C1.11		Are there any people from the underlying population that the data bank covers whose data are not collected in the data bank (e.g., people without a national insurance number, people who are registered for private care)?	No/yes	Manual entry
C1.11.1	Population coverage details	If yes to the question above, which subpopulation(s) are not covered by the data bank?	Free text	Manual entry
C1.11.2		What percentage of the underlying population is covered by the data bank?	Unit: %	Manual entry
C1.12	Time span - first collection	On what date did records first start entering the data bank?	DDMMYYYY	Manual entry
C1.13	Time span - last collection		DDMMYYYY	Manual entry
C1.14	Care setting	Type of care setting(s) covered by data bank.	General population/primary care/secondary care/tertiary care/other	Manual entry
C1.14.1	Care setting, other	If 'other,' description of the setting of care.	Free text	Manual entry

### Metadata category: Data bank - access

Var ID	Var name	Description	Standards	Entry
C1.1	Data bank ID	A persistent identifier for a data bank. This may be created by the catalogue maintainer on first entry of a data bank. It provides links across tables.		
C2.1	DAPs	List of DAPs that are listed in the catalogue as having (conditional) permission to access (an extract of) the data bank	Should take values from A1.1	Automatically populated when a contributor enters A2.3 Ins-data sources and data banks-Is DAP as yes and a data bank with corresponding Data bank ID is selected
C2.2	Data controller	The name of the institution or organisation that is responsible for governance of the data bank.	Free text	Manual entry
C2.3	Governance details	If available, provide documents or webpages that describe the overall governance of the data source (governing data access or utilisation for research purposes by existing DAPs)	Link to documents/URL	Manual entry
C2.3.1	Committee data access	Is there a committee that determines access to the data source by the DAPs that are already listed?	No/yes	Manual entry
C2.4	Policy data access	If available, provide documents or webpages that describe the policy for access to the data bank.	Link to documents/URL	Manual entry
C2.5	Informed consent	Is informed consent required for use of the data for research purposes?	Required for general use/required for all studies/required for intervention studies/waiver/other	Manual entry
C2.5.1	Informed consent other	If other, describe the conditions when informed consent is required.	Free text	Manual entry
C2.6	Access to identifiable data	Can identifiable data be accessed in the data bank (including patient/practitioner name/practice name)?	Free text	Manual entry
C2.6.1	Route to access to identifiable data	If yes above, what is the route to access this information? What permission is required?	No/yes	Manual entry
C2.7	Access to subject details	Can individual patients/practitioners/practices be contacted in the data bank?	No/yes	Manual entry
C2.7.1	Route to access to subject details	If yes above, what is the route to access this information? What permission is required?	Free text	Manual entry
C2.8	Audit possibility	Are external parties allowed to audit the data? For example, is it possible for an external party to audit the quality or validity of the data bank?	No/yes	Manual entry
C2.9	Approval for publication	Is an approval needed for a DAP to publish the results of a study using the data source?	No/yes	Manual entry
C2.10	Third-party access	Can (an extract of) the data bank be accessed with permission by a third party?	No/yes	Manual entry
C2.10.1	Third-party access conditions	If yes above, describe the conditions under which third-party access may be granted (another organisation that is not a data originator or a DAP)	Free text	Manual entry
C2.11	Non-EU EEA access	Can (an extract of) the data bank be accessed with permission by a non-EU/EEA institution?	No/yes	Manual entry
C2.11.1	Non-EU EEA access conditions	If yes above, describe the conditions under which third-party access may be granted	No/yes	Manual entry
C2.12	Standard operating procedures	Is there a standard operating procedure document that defines the processes and procedures for data capture and management?	No/yes	Manual entry
C2.13	Biospecimen access	If the data bank contains biospecimens (e.g., tissue samples), can these be retrieved?	No/yes	Manual entry
C2.13.1	Biospecimen access conditions	If yes above, describe the conditions under which permission to retrieve biospecimens may be granted.	Free text	Manual entry

EEA = European Economic Area ; EU = European Union; ID = identifier.

### Metadata category: Data bank - qualification

Var ID	Var name	Description	Standards	Entry
C1.1	Data bank ID	A persistent identifier for a data bank. This may be created by the catalogue maintainer on first entry of a data bank. It provides links across tables.		
C3.1	Data bank qualification	Has the data bank successfully undergone a qualification process (e.g., from the EMA)?	No/yes	Manual entry
C3.1.1	Description of qualifications	If yes, describe the qualification(s) granted.	Free text	Manual entry

EMA = European Medicines Agency; ID = identifier.

### Metadata category: Data bank - originator

Var ID	Var name	Description	Standards	Entry
C1.1	Data bank ID	A persistent identifier for a data bank. This may be created by the catalogue maintainer on first entry of a data bank. It provides links across tables.		
C4.1	Originator	Name of the organisation that maintains the collection of records.	Free text	Manual entry
C4.1.1	Originator email contact	Contact email address of the originator organization	Free text; must take form "prefix@domain"	Manual entry
C4.2	Type of organisation	Description of the type of organisation that is originator of the data bank.	Academic institution/civic authority/government agency/healthcare payer/network of primary care practices/non-profit organisation/pharmaceutical industry/private organisation/public health authority/research centre/statistical authority	Manual entry
C4.2.1	Type of organisation, other	If other, description of the type of originator.	Free text	Manual entry
C4.3	Description of data collection	Describe the process of collection and recording of data in the data bank. This could include the tools, such as surveys, used, or a description of the system that the originator uses to gather data and store it the data bank.	Free text	Manual entry
C4.4	Reason data bank is sustained	Description of the reason why the data bank is sustained by the organisation (e.g., for surveillance, clinical purposes, financial or administrative purposes, research purposes).	Free text	Manual entry
C4.5	Date established	Date that the data bank was first established.	DDMMYYYY	Manual entry
C4.6	Finance source	Specify the main financial support sources for the data bank in the last 3 years. Select all that apply.	Funding by own institution/national, regional, or municipal public funding/European public funding/funding from industry or contract research/funding from public-private partnership/funds from patients organisations, charity and foundations/other	Manual entry
C4.6.1	Finance source, other	Specify	Free text	Manual entry

### Metadata category: Data bank - prompt

Var ID	Var name	Description	Standards	Entry
C1.1	Data bank ID	A persistent identifier for a data bank. This may be created by the catalogue maintainer on first entry of a data bank. It provides links across tables.		
C5.1	Data bank family	Which of the following families of data banks best describe this data bank?	Hospital discharge records/primary care medical records/pharmacy dispensation records/birth registry/induced terminations registry/congenital anomaly registry/inhabitant registry/registration with healthcare system/outpatient visit records/emergency care discharge records/exemptions from co-payment/diagnostic tests or procedures reimbursement/death registry/cancer registry/other disease registry/vaccine registry/biobank/administrative claims / spontaneous reporting of adverse drug reactions	Manual entry
C5.1.1	Data bank family, other	If 'other,' describe the type of the data bank.	Free text	Manual entry
C5.2	Data bank prompt	What prompts the creation of a record in the data bank? e.g., hospital discharge, specialist encounter, dispensation of a medicinal product, recording of a congenital anomaly	Free text	Manual entry
C5.3	Data bank prompt exception	Describe any exceptions when the data bank prompt would not lead to creation of a record.	Free text	Manual entry
C5.4	Unit of observation	Based on the prompt, what is the unit of observation of a record (e.g., person, prescription)?	Free text	Manual entry
C5.5	Multiple entries	Can there be multiple entries for a single person in the data bank? For example, may a person contribute multiple records to the data bank?	No/yes	Manual entry

	a category: Data bank - data :			
This table	captures information that is found in th	ne data model (or dictionary) of a data bank and relates to the catalogue table in the data dictionary, if an English language translation is provided  Description  A persistent identifier for a data bank. This may be created by the catalogue maintainer on first entry of a data bank. It provides links across tables.	Standards	Entry
06.1 <b>06.1.1</b>	Data dictionary present  Data dictionary document	Are a data dictionary and a data model available?  If available, a list of data dictionary and data model documents is entered.  The data dictionary contains the list of variables captured in the data bank, according to the data model, with descriptions.	No/yes Links to documents	Manual entry Manual entry
06.1.2 06.1.3	Data bank number of tables Data dictionary item names	Number of separate tables within the data bank  Data dictionary: inclusion of data item names	Numeric Yes, for all variables; Yes, but not for all variables; No	Manual entry  Manual entry
C6.1.4 C6.1.5	Data dictionary values  Data dictionary algorithms	Data dictionary: inclusion of codes, value ranges, & measurement units  Data dictionary: inclusion of formulae & algorithms used for derived variables	Yes, for all variables; Yes, but not for all variables; No Yes, for all derived variables; Yes, but not for all derived variables;	Manual entry  Manual entry
06.1.6	Data dictionary language	Languages in which that the data bank dictionary is recorded	No; Not required as source does not contain derived variables List of languages linked to ISO 639 codes (https://www.iso.org/iso-639-language-codes.html)	Manual entry
06.1.7 <b>0.6.2</b> 06.3	Data dictionary summary  Data bank language  Processed tables	If available, a summary data dictionary or abridged version is entered  Languages in which that the records in the data bank are recorded  Does the data bank contain pre-processed tables (i.e., curated by an	Links to documents  List of languages linked to ISO 639 codes (https://www.iso.org/iso-639-language-codes.html)  No/yes	Manual entry  Manual entry  Manual entry
6.3.1 6.4	Processed tables description  Unique identifier	organisation other than the DAP)?  If yes to the above, a description of the tables that are pre-processed  Is there a unique identifier for a person in the data bank?	Free text No/yes	Manual entry  Manual entry, in future implementations of the
6.4.1	Unique identifier description	Describe the variable that is used as a unique identifier for a person in the	Free text	catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of functions  Manual entry, in future implementations of the
0.4.1	Onique identifier description	data bank? If the unique identifier is not at level of a person (for example hospital encounter), describe how this translated to an individual level.	Free text	catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of functions
6.5	Geographic regions	Are data on geographic region available?	No/yes	Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of functions
6.6	Familylinkage	Is any linkage available in the data bank between any of the following persons?	Household/mother-child/father-child/sibling	Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of
6.6.1	Family linkage routine	Is familial linkage created routinely or can linkage be performed on an adhoc basis?	Routine/ad hoc	functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English
6.6.2	Family linkage availability	Is familial linkage available for all of the data bank population or a subset of individuals (or records)?	Full/subset	language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English
6.6.3	Family linkage availability details	If a familial linkage is available for a subset of individuals (or records) only, provide a short description of the subset.	Free text	language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted
6.7	Sociodemographics included	Which of the following sociodemographic information is included? Select	None/age/sex/gender/ethnicity/country of origin/socioeconomic	automatically from the data dictionary, if an English language version is uploaded, using scripts of functions  Manual entry, in future implementations of the
<b>6</b> 9	Lifertyle frot ove in alveded	all that apply.	status/marital status/education level/type of residency/living in rural area/health area/deprivation index/pharmaceutical copayment/other	catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of functions
6.8	Lifestyle factors included	Which of the following lifestyle information is included? Select all that apply	/. None/tobacco use/alconol use/trequency of exercise/other	Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of functions
6.9	Diagnosis codes included	Are diagnostic codes included?	No/yes	Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of functions
6.9.1	Diagnosis code vocabulary	If yes, what vocabulary is used? Select from the following:	ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other	Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of
6.9.2 6.9.3	Diagnosis code not coded  Diagnosis, other	If Not coded (Free text), approximately what percentage of records are not coded?  Is other information on diagnoses of patient outcomes recorded, not in the		functions  Manual entry  Manual entry; in future implementations of the
	g	form of diagnostic codes?		catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of functions
6.10	Hospital admission discharge	Is information on hospital admission and/or hospital discharge available?	No/yes	Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of functions
6.10.1	ICU admission	Is information on intensive care unit admission available?	No/yes	functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of
6.11	Cause of death	Is cause of death available?	No/yes	language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English
6.11.1	Cause of death vocabulary	If yes, what vocabulary is used? Select from the following:	ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other	automatically from the data dictionary, if an English language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted
6.11.2	Cause of death not coded	If Not coded (Free text), approximately what percentage of records are not		catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of functions  Manual entry
5.11.2 5.11.3	Cause of death not coded  Cause of death code, other	If Not coded (Free text), approximately what percentage of records are not coded?  If 'other,' what vocabulary is used?	Unit: %, not applicable  Free text	Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English
6.12	Rare diseases	Are rare diseases (<1 in 2000 people) captured?	No/yes	language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English
6.13	Prescriptions included	Is information on prescription of medications included?	No/yes	language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted
6.13.1	Prescriptions vocabulary	If yes, what vocabulary is used? Select from the following:	ATC/RxNorm/EphMRA/ALT/DrugBank/Not coded (Free text)/Other	automatically from the data dictionary, if an English language version is uploaded, using scripts of functions  Manual entry, in future implementations of the
				catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of functions
6.13.2 6.13.3	Prescriptions not coded  Prescriptions vocabulary, other	If Not coded (Free text), approximately what percentage of records are not coded?  If 'other,' what vocabulary is used?	Unit: %, not applicable  Free text	Manual entry  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English
6.14	Dispensings included	Is information on dispensing of medications included?	No/yes	language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted
6.14.1	Dispensings vocabulary	If yes, what vocabulary is used? Select from the following:	ATC/RxNorm/EphMRA/ALT/DrugBank/Not coded (Free text)/Other	automatically from the data dictionary, if an English language version is uploaded, using scripts of functions  Manual entry, in future implementations of the
				catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of functions
5.14.2 5.14.3	Dispensings not coded  Dispensings vocabulary, other	If Not coded (Free text), approximately what percentage of records are not coded?  If 'other,' what vocabulary is used?	Unit: %, not applicable  Free text	Manual entry  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English
6.15	Product information	Is product information available? Select all items that apply.	Brand name/batch number/formulation/strength/package size	language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted
6.15.1	Product information, product	If product information is included, what vocabulary is used to describe the	ART 57/IFA GmbH/EQDM/SPN/MTHSPL/Not coded (Free text)/Other	automatically from the data dictionary, if an English language version is uploaded, using scripts of functions  Manual entry, in future implementations of the
	vocabulary	product?		catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of functions
6.15.2	Product vocabulary, other	If 'other,' what vocabulary is used?	Free text	Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of functions
6.15.3	Product information, substance vocabulary	If substance information is included, what vocabulary is used to describe the substance?	e ART 57/IFA GmbH/EQDM/SPN/MTHSPL/Not coded (Free text)/Other	Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of
6.15.4	Substance vocabulary, other	If 'other,' what vocabulary is used?	Free text	functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English
6.15.5	Other medicines information	Is other information on medicines or products included?	No/yes	language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English
6.15.6	Other medicines information details	If yes to the above, select all the items that apply.	Dose/dosage regime/route of administration/product information	language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted
6.16	ATMP	Is information on advanced therapy medicinal products included?	No/yes	automatically from the data dictionary, if an English language version is uploaded, using scripts of functions  Manual entry, in future implementations of the
	· · · · · · ·	io miormatori sir autoriosa triorapy modelina producte mioragea.	TVS yes	catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions
5.17	Contraception	Is information on contraceptives included?	No/yes	Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of functions
5.17.1	Emergency contraception	If yes, is information on emergency contraceptives included?	No/yes	Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of
5.18	Indication for use	If medicines information is captured, is the indication for use recorded?	No/yes/not applicable	Ianguage version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis
5.18.1	Indication vocabulary	If yes, what vocabulary is used? Select from the following:	ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other	language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted
5.18.2	Indications not coded	If Not coded (Free text), approximately what percentage of records are not		automatically from the data dictionary, if an English language version is uploaded, using scripts of functions  Manual entry
.18.3	Indications not coded  Indication vocabulary, other	coded?  If 'other,' what vocabulary is used?	Free text	Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of
5.19	Administration vaccines included	Is information on the administration of vaccines included?	No/yes	language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis
.19.1	Administration other injectable medicines	Is information on the administration of other injectable medicines included?	No/yes	language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted
.20	Medical devices	Is information on medical devices included?	No/yes	automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions  Manual entry, in future implementations of the
				catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of functions
.21	Procedures included	Is information on procedures (e.g., diagnostic tests, therapeutic, surgical) included?	No/yes	Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions
22	Procedures vocabulary	If yes, what vocabulary is used? Select from the following:	ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other	Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of
22.1 22.2	Procedures not coded  Procedure vocabulary, other	If Not coded (Free text), approximately what percentage of records are not coded?  If 'other,' what vocabulary is used?	Unit: %, not applicable Free text	functions  Manual entry  Manual entry; in future implementations of the
				catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions
.22.3	Procedure results	Are results of procedures available?	No/yes	Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions
.22.4	Procedure results vocabulary	If yes, what vocabulary is used? Select from the following:	ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/MedDRA/OPCS/CCS/EDC/Not coded (Free text)/Other	Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of
.22.5	Procedure results not coded  Procedure results vocabulary, other	If Not coded (Free text), approximately what percentage of records are not coded?  If 'other,' what vocabulary is used?	Unit: %, not applicable Free text	functions  Manual entry  Manual entry; in future implementations of the
	,			catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions
.23	Clinical measures included	Is information on clinical measures included (e.g., BMI, blood pressure)?	ivo/yes	Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions
			No/yes	Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of
.24	Healthcare centre	Is information on the healthcare centre (e.g., pharmacy, general practice, hospital) available?		
	Healthcare centre  Healthcare provider		No/yes	functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis
24.1		hospital) available?  Is information on the person providing healthcare (e.g., physician,	No/yes No/yes	functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted
.24.1 25	Healthcare provider	hospital) available?  Is information on the person providing healthcare (e.g., physician, pharmacist, specialist) available?		functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions  Manual entry, in future implementations of the
24.1 25 25.1	Healthcare provider  Genetic data  Genetic data vocabulary	Is information on the person providing healthcare (e.g., physician, pharmacist, specialist) available?  Is genotyping information available?  If yes, what vocabulary is used? Select from the following:	No/yes  OGG/FG/GO/EGO/SOPHARM/PHARE/other	functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions
5.24.1 5.25 5.25.1	Healthcare provider  Genetic data	hospital) available?  Is information on the person providing healthcare (e.g., physician, pharmacist, specialist) available?  Is genotyping information available?	No/yes	functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted
5.24.1 5.25 5.25.1	Healthcare provider  Genetic data  Genetic data vocabulary	Is information on the person providing healthcare (e.g., physician, pharmacist, specialist) available?  Is genotyping information available?  If yes, what vocabulary is used? Select from the following:	No/yes  OGG/FG/GO/EGO/SOPHARM/PHARE/other  Free text	Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of
5.24.1 5.25 5.25.1 5.25.2	Healthcare provider  Genetic data  Genetic data vocabulary  Genetic data vocabulary, other	Is information on the person providing healthcare (e.g., physician, pharmacist, specialist) available?  Is genotyping information available?  If yes, what vocabulary is used? Select from the following:	No/yes  OGG/FG/GO/EGO/SOPHARM/PHARE/other  Free text	Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions
6.24.1 6.25 6.25.2 6.25.3	Healthcare provider  Genetic data  Genetic data vocabulary  Genetic data vocabulary, other  Genetic data summary	Is information on the person providing healthcare (e.g., physician, pharmacist, specialist) available?  Is genotyping information available?  If yes, what vocabulary is used? Select from the following:  If 'other,' what vocabulary is used?	No/yes  OGG/FG/GO/EGO/SOPHARM/PHARE/other  Free text  Free text	functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englis language version is uploaded, using scripts of functions
6.24.1 6.25 6.25.1 6.25.3 6.26.1	Healthcare provider  Genetic data  Genetic data vocabulary  Genetic data vocabulary, other  Genetic data summary  Biomarker data	Is information on the person providing healthcare (e.g., physician, pharmacist, specialist) available?  Is genotyping information available?  If yes, what vocabulary is used? Select from the following:  If 'other,' what vocabulary is used?  A short summary of how genetic information is captured in the data source.  Is biomarker information available?	No/yes  OGG/FG/GO/EGO/SOPHARM/PHARE/other  Free text  No/yes	functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englist language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englist language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englist language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englist language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englist language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englist language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englist language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englist language version is uploaded, using scripts of functions
6.24.1 6.25 6.25.1 6.25.3 6.26 6.26.1	Healthcare provider  Genetic data  Genetic data vocabulary  Genetic data vocabulary, other  Genetic data summary  Biomarker data  Biomarker data vocabulary	Is information on the person providing healthcare (e.g., physician, pharmacist, specialist) available?  Is genotyping information available?  If yes, what vocabulary is used? Select from the following:  If 'other,' what vocabulary is used?  A short summary of how genetic information is captured in the data source.  Is biomarker information available?  If yes, what vocabulary is used? Select from the following:	No/yes  OGG/FG/GO/EGO/SOPHARM/PHARE/other  Free text  No/yes  BMO/SMASH/FOBI/other	functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of functions
6.24 6.24.1 6.25 6.25.1 6.25.2 6.26.3 6.26.3	Healthcare provider  Genetic data  Genetic data vocabulary  Genetic data vocabulary, other  Genetic data summary  Biomarker data  Biomarker data vocabulary	Is information on the person providing healthcare (e.g., physician, pharmacist, specialist) available?  Is genotyping information available?  If yes, what vocabulary is used? Select from the following:  If 'other,' what vocabulary is used?  A short summary of how genetic information is captured in the data source.  Is biomarker information available?  If yes, what vocabulary is used? Select from the following:	No/yes  OGG/FG/GO/EGO/SOPHARM/PHARE/other  Free text  No/yes  BMO/SMASH/FOBI/other	functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English language version is uploaded, using scripts of functions

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C6.27.1	Patient-generated data summary	A short summary of how patient-generated information (e.g., from wearable devices) is captured in the data bank	e Free text	Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Engl language version is uploaded, using scripts of functions
C6.28	Quality of life included	Are quality of life measures available? Select all that apply.	AQoL-8D/QOLS/MQOL/MQOL-E/HRQOL/WHOQOL/EQ5D/15D/SF-36/SF-6D/HUI/other	Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Engl language version is uploaded, using scripts of functions
C6.28.1	Quality of life, other	If 'other,' specify additional quality of life measures.	Free text	Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Engl language version is uploaded, using scripts of functions
C6.29	Costs	Is information on costs of healthcare available?	No/yes	Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Engl language version is uploaded, using scripts of functions
C6.30	Free text	Is free text information available?	No/yes	Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Engl language version is uploaded, using scripts of functions
C6.30.1	Use of NLP	Is natural language processing used to process free text information into standardised information?	No/yes/not applicable	Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Engl language version is uploaded, using scripts of functions
C6.30.2	Details of NLP	If natural language processing is used, provide a summary description of how natural language processing is used.	Free text	Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Engl language version is uploaded, using scripts of functions
C6.30.3	Deidentified text	Are procedures in place to de-identify or remove personal information from free text?	No/yes/not applicable	Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Engl language version is uploaded, using scripts of

BMI = body mass index; DAP = data access provider; ID = identifier; NLP = Natural language processing

.Classified as internal/staff contractors by the European Medicines Agency

# Metadata category: Data bank - quantitative descriptors

\* The date of last update (entry) of quantitative descriptor variables will be automatically presented alongside each of these variables in the catalogue (collected in table M)

Var ID	Var name	Description	Standards	Entry
C1.1	Data bank ID	A persistent identifier for a data bank. This may be created by the catalogue maintainer on first entry of a data bank. It provides links across tables.		
C7.1	Population size	Total number of unique individuals with records captured in the data bank (most recent count). In the catalogue, this will accommodate counts per year.	Numeric	Manual entry; in future implementations scripts or functions could work together with a common data model to extract this information directly from a data bank
C7.1.1	Population size active	Number of unique, active, or currently registered individuals with records captured in the data source (most recent count). In the catalogue, this will accommodate counts per year.	Numeric	Manual entry; in future implementations scripts or functions could work together with a common data model to extract this information directly from a data bank
C7.2	Number of individuals with biological samples	Number of unique individuals with records of biological samples (e.g., blood, urine) (most recent count). In the catalogue, this will accommodate counts per year.	Numeric	Manual entry; in future implementations scripts or functions could work together with a common data model to extract this information directly from a data bank
C7.3	Population size by age	Total number of unique individuals with records captured in the data bank (most recent count), stratified by age	Numeric, for each of the following categories: 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 75 years), adults (76 years and over)	data model to extract this information directly
C7.3.1	Population size active by age	Number of unique, active, or currently registered individuals with records captured in the data bank (most recent count), stratified by age	Numeric, for each of the following categories: 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 75 years), adults (76 years and over)	data model to extract this information directly
C7.4	Median age data bank	Median age of individuals within the data bank	Numeric	Manual entry; in future implementations scripts or functions could work together with a common data model to extract this information directly from a data bank
C7.5	Proportion female data bank	Proportion of females in the data bank	Unit: %	Manual entry; in future implementations scripts or functions could work together with a common data model to extract this information directly from a data bank
C7.6	Proportion ethnicity data bank	Proportion of people per ethnicity in the data bank	Unit: %, per ethnicity group	Manual entry; in future implementations scripts or functions could work together with a common data model to extract this information directly from a data bank

### Metadata category: Data bank - updates and lag time

Var ID	Var name	Description	Standards	Entry
C1.1	Data bank ID	A persistent identifier for a data bank. This may be created by the catalogue maintainer on first entry of a data bank. It provides links across tables.		
C8.1	Data bank refresh	Average number of days between refresh of data bank with new records	Unit: days	Manual entry
C8.2	Data bank refresh period	If data are refreshed on fixed dates (e.g., every June and December), when are the refreshes scheduled? Select all that apply from the following:	January/February/March/April/May/June/July/August/September/Oct ober/November/December	Manual entry
C8.3	Data bank last refresh	Date of last update/refresh	DDMMYYY	Manual entry
C8.4	Data bank lag	How long is the lag time after refresh before a record can be extracted? (e.g., a lag time may occur if the originator conducts quality checks)	Unit: days	Manual entry
C8.5	Data bank preservation	Are records preserved in the data bank indefinitely?	No/yes	Manual entry
C8.5.1	Data bank preservation length	If no to the above, for how long are records preserved in the data bank?	Unit: years	Manual entry
C8.6	Data bank changes	Provide a description of any major changes to the data bank that have occurred over time, including updates in its data model, prompts, or underlying population.	Free text	Manual entry

#### Metadata category: Data bank - quality

Var ID	Var name	Description	Standards	Entry
C1.1	Data bank ID	A persistent identifier for a data bank. This may be created by the catalogue maintainer on first entry of a data bank. It provides links across tables.		
C9.1	Number of records	Total number of unique records captured in the data bank (most recent count)	Numeric	Manual entry
C9.2	Number of excluded records	If records were excluded following quality checks or a quality assurance process, the total number of unique records that were excluded	Numeric	Manual entry
C9.3	Comment completeness missing values	Describe the completeness of the data bank (e.g., variables with more or fewer missing values).	Free text	Manual entry
C9.3.1	Comment completeness missing values over time	Describe any changes in completeness of the data bank (e.g., variables with more or fewer missing values) that have occurred over time.	Free text	Manual entry
C9.3.2	Comment completeness missing values subpopulations	Describe any differences in completeness of the data bank (e.g., variables with more or fewer missing values) across subpopulations of people in the data bank.	Free text	Manual entry
C9.4	Comment quality	Describe the quality of the data bank (e.g., variables with more or fewer missing values).	Free text	Manual entry
C9.4.1	Comment quality over time	Describe any changes in quality of the data bank (e.g., variables with more or fewer missing values) that have occurred <i>over time</i> .	Free text	Manual entry
C9.4.2	Comment quality subpopulations	Describe any differences in quality of the data bank (e.g., variables with more or fewer missing values) across subpopulations of people in the data bank.	Free text	Manual entry
C9.5	Access validation	Can validity of the data in the data bank be verified, e.g., by review of origin medical charts?	No/yes	Manual entry
C9.5.1	Data quality check and validation frequency	How often are data quality checks and validation steps conducted on the data bank?	Free text	Manual entry
C9.5.2	Data quality check and validation methods	What methods or processes are applied for data quality checks and validation steps conducted on the data bank?	Free text	Manual entry
C9.5.3	Correction of illogical values	What methods or processes are applied to correct illogical values in the data bank?	Free text	Manual entry
C9.5.4	Data bank completeness results	What methods or processes are applied to check completeness of the data bank?	Free text	Manual entry
C9.5.5	Data quality check and validation results	A table of summary measures of percentage completeness of variables in the data bank (per year) can be uploaded. The table variables should match the variables in the data dictionaries of the data bank. Upload in a standard form is envisioned, to facilitate visualisation.	Upload	Manual entry
C9.5.6	Data quality check and validation results publication	If available, provide a link to a publication of the data quality check and validation results.	Allow individual AMA format citations / URL to list of publications.	Manual entry

### Metadata category: Data bank - studies

\*This table is created and automatically updated for institutions when there is an entry for the institution in Study-data sources and data banks-data bank name

Var ID	Var name	Description	Standards	Entry
C1.1	Data bank ID	A persistent identifier for a data bank. This may be created by the catalogue maintainer on first entry of a data bank. It provides links across tables.		
C10.1	Data bank studies	A list of IDs of studies that have been conducted using the data bank that are recorded in the catalogue		Automatically populated when the data bank ID is entered in F3.4 - Study - data sources and data banks

### Metadata category: Data bank - publications

Var ID	Var name	Description	Standards	Entry
C1.1	Data bank ID	A persistent identifier for a data bank. This may be created by the catalogue maintainer on first entry of a data bank. It provides links across tables.		
C11.1	Data bank website	If applicable, a dedicated website for the data bank	URL	Manual entry
C11.2	Data bank publications	A list of peer-reviewed papers describing the data bank or link to a webpage with this list	Allow individual AMA format citations / URL to list of publications.	Automatically populated when an entry is made in F7.2-Study report, using the study IDs (F1.1) where the data source is selected in F3.3-Data sources and data banks
C11.3	Data bank, other information	A list of URLs to other relevant resources describing the data bank o its use in pharmacoepidemiologic studies	r URL	Manual entry

Metadata category: Common data model - general
\*This will be completed by institutes only when a CDM is utilised in a particular study

Var ID	Var name	Description	Standards	Entry
D1.1	CDM ID	A persistent identifier for a CDM. This may be created by the catalogue maintainer on first entry of a CDM. It provides links across tables.	•	
D1.2	CDM name	Name by which the common data model is most frequently referred. Multiple from the list may be selected.	OMOP/ConcepTION/Nordic/Sentinel/PCORnet/VSD/i2b2/CDISC SDTM/PEDSnet/other	Manual entry
D1.2.1	CDM name, other	If 'other,' provide the name of the CDM.	Free text	Manual entry
D1.3	CDM maintainer	Name of the organisation or institute that is responsible for developing and maintaining the CDM.	Free text	Manual entry
D1.4	CDM website	If there is a website for the CDM, provide it here.	URL	Manual entry
D1.4.1	CDM model	If a website is not available for the CDM, upload documentation of the CDM model.	Document uploaded	Manual entry
D1.5	CDM tables	If there is a website for the CDM, provide a link to a description of the CDM tables.	URL	Manual entry
D1.6	CDM documentation	Provide any further resources describing the CDM and tools or software to utilise it.	URL	Manual entry

CDM = common data model; ID = identifier.

### Metadata category: Common data model - vocabulary

Var ID	Var name	Description	Standards	Entry
D1.1	CDM ID	A persistent identifier for a CDM. This may be created by the catalogue maintainer on first entry of a CDM. It provides links across tables.		
D2.1	Standardised vocabularies	Are data mapped to standardised vocabularies during ETL to the CDM?	No/yes	Manual entry
D2.2	CDM vocabulary events	If yes, what vocabularies are used for events, such as diagnoses?	ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/ MedDRA/OPCS/Not coded (Free text)/Other	Manual entry
D2.2.1	CDM vocabulary events, other	If 'other,' what vocabulary is used?	Free text	Manual entry
D2.3	CDM vocabulary medicines	If yes, what vocabularies are used for medicines or vaccines?	ATC/RxNorm/ICPC/ICD9/ICD10/ICD11/Read/SNOMED/ SNOMED CT/ MedDRA/OPCS/ART 57/Not coded (Free text)/Other	Manual entry
D2.3.1	CDM vocabulary medicines, other	If 'other,' what vocabulary is used?	Free text	Manual entry
D2.4	CDM vocabulary procedures	If yes, what vocabularies are used for procedures?	ICPC/ICD9/ICD10/ICD1/Read/ SNOMED/SNOMED CT/ MedDRA/OPCS/Not coded (Free text)/Other	Manual entry
D2.4.1	CDM vocabulary procedures, other	If 'other,' what vocabulary is used?	Free text	Manual entry

CDM = common data model; ETL = extract, transform, load; ID = identifier.

Metadata category: Network - overview

\* The network studies will be automatically updated on entry of metadata to [stu-institutions-study network]

Var ID	Var name	Description	Standards	Entry
E1.1	Network ID	A persistent identifier for a network. This may be created by the catalogue maintainer on first entry of a network. It provides links across tables.		
E1.2	Network name	Official name of the network as used in EU projects	Free text	Manual entry
E1.3	Network acronym	Official acronym of the network, if applicable	Free text	Manual entry
E1.4	Network website	A link to a dedicated website for the network	URL	Manual entry
E1.5	Network contact person	Name of contact for network	Free text	Manual entry
E1.6	Network contact email	Contact email address for network contact	Free text	Manual entry
E1.7	Network institutions	List of institutions that are within the network. Select from the following list of institutions.	Should take values within A1.1. If required value is not present in A1.1, an entry must be made in table A1-Institution-role	Manual entry
E1.8	Network studies	List of studies that were conducted within the network.	Should take values within F1.1. If required value is not present in F1.1, an entry must be made in table F1-Study-institutions	Automated entry, populated with the corresponding value of F1.1 when an entry is made in F1.8.

EU = European Union; ID = identifier.

Metadata category: Study - institutions

\* This is envisioned to be updated on a study-by-study basis and may link to the EU PAS register

Var ID	Var name	Description	Standards	Entry
F1.1	Study ID	A persistent identifier for a study. This may be created by the catalogue maintainer on first entry of a study. It provides links across tables.		
F1.2	Study title	Unique study title	Free text	Manual entry. If a persistent Study ID is maintained between this catalogue and the EUPAS register, this may be automatically populated on creation of an entry to the EUPAS register
F1.3	Study institution	Name of lead institution that conducted the study	Should take value within A1.1.	Manual entry. If a persistent Study ID is maintained between this catalogue and the EUPAS register, this may be automatically populated on creation of an entry to the EUPAS register
F1.4	Study institution contact name	Name of institution contact for study	Free text	Manual entry. If a persistent Study ID is maintained between this catalogue and the EUPAS register, this may be automatically populated on creation of an entry to the EUPAS register
F1.5	Study institution contact email	Email of institution contact for study	Free text; must take form "prefix@domain"	Manual entry. If a persistent Study ID is maintained between this catalogue and the EUPAS register, this may be automatically populated on creation of an entry to the EUPAS register
F1.6	Study institution contact ORCID	If available, an ORCID number of the investigator named above	Numeric	Manual entry. If a persistent Study ID is maintained between this catalogue and the EUPAS register, this may be automatically populated on creation of an entry to the EUPAS register
F1.7	Additional institutions	List the names of any additional institutions that contributed to the study	Should take value within A1.1.	Manual entry. If a persistent Study ID is maintained between this catalogue and the EUPAS register, this may be automatically populated on creation of an entry to the EUPAS register
F1.8	Study network	If relevant, name of the network associated with the study	Should take value within E1.1.	Manual entry. If a persistent Study ID is maintained between this catalogue and the EUPAS register, this may be automatically populated on creation of an entry to the EUPAS register

Metadata category: Study - protocols

\* This is envisioned to be updated on a study-by-study basis and may link to the EU PAS register

Var ID	Var name	Description	Standards	Entry
F1.1	Study ID	A persistent identifier for a study. This may be created by the catalogue maintainer on first entry of a study. It provides links across tables.		
F2.1	Protocol link	A link to the latest version of the protocol, if published	URL	Manual entry
F2.2	EU PAS number	If registered to EU PAS registry, the EU PAS number of the study	Numeric	Manual entry
F2.3	Protocol document	An uploaded version of the protocol, if a URL or EU PAS entry is not available	Uploaded document	Manual entry
F2.4	Type of study	Select 1 of the following types of study	PASS/PAES/external control/post-marketing surveillance/other	Manual entry. If a persistent Study ID is maintained between this catalogue and the EUPAS register, this may be automatically populated on creation of an entry to the EUPAS register
F2.5	Population	A short description of the study population	Free text	Manual entry. If a persistent Study ID is maintained between this catalogue and the EUPAS register, this may be automatically populated on creation of an entry to the EUPAS register
F2.6	Interventions	A short description of the study interventions	Free text	Manual entry. If a persistent Study ID is maintained between this catalogue and the EUPAS register, this may be automatically populated on creation of an entry to the EUPAS register
F2.7	Comparators	A short description of the study comparators	Free text	Manual entry. If a persistent Study ID is maintained between this catalogue and the EUPAS register, this may be automatically populated on creation of an entry to the EUPAS register
F2.8	Outcomes	A short description of the study outcomes	Free text	Manual entry. If a persistent Study ID is maintained between this catalogue and the EUPAS register, this may be automatically populated on creation of an entry to the EUPAS register
F2.9	Timing start	The date of the start of the study period. For example, the date when patients are first included in the study.	DDMMYYY	Manual entry. If a persistent Study ID is maintained between this catalogue and the EUPAS register, this may be automatically populated on creation of an entry to the EUPAS register
F2.10	Timing end	The date of the end of the study period. For example, the last date of patient follow-up.	DDMMYYY	Manual entry. If a persistent Study ID is maintained between this catalogue and the EUPAS register, this may be automatically populated on creation of an entry to the EUPAS register
F2.11	Setting	A short description of the study setting	Free text	Manual entry. If a persistent Study ID is maintained between this catalogue and the EUPAS register, this may be automatically populated on creation of an entry to the EUPAS register

EU PAS = European Union electronic register of post-authorisation studies; ID = identifier.

Metadata category: Study - data sources and data banks

As a part of the recommendations in the Good Practice Guide, four additional metadata variables have been recommended for addition to this table (listed at the end of the table).

These additional variables provide additional information to support use cases relating to replicability of studies and understanding quality of study variables created using data sources and data banks in the catalogue.

Var ID	Var name	Description	Standards	Entry
F1.1	Study ID	A persistent identifier for a study. This may be created by the catalogue maintainer on first entry of a study. It provides links across tables.		
F3.1	Number of data sources	Total number of data sources included in the study	Numeric	Manual entry
F3.2	Number of data banks	Total number of data banks included in the study	Numeric	Manual entry
F3.3	Data source name	Names of data sources used in the study. Select from the following list.	Should take values in B1.1	Manual entry
F3.4	Data bank name	Names of data banks used in the study. Select from the following list.	Should take values in C1.1	Manual entry
F3.5	Data extraction date	Date on which the study data was extracted	DDMMYYYY	Manual entry
F3.6	Institution performing extraction	Names of the institutes or organisations that extracted raw data for the study. Select from the following list	Should take values in A1.1	Manual entry
F3.7	Software data extraction	Name of software used for data extraction (i.e., retrieval of records from data banks)	Free text	Manual entry
F3.7.1	Software data extraction version	Version of software used for data extraction (i.e., retrieval of records from data banks)	Free text	Manual entry
F3.7.2	Restrictions in the data bank extraction	Description of the limitations imposed to the records or values extracted from each data bank (e.g., only records of persons born after 1950; only diagnostic codes belonging to a specified code list)	Free text	Manual entry
F3.8	Software data processing	Name of software used for data processing (i.e., creation of the analysis data set(s))	Free text	Manual entry
F3.8.1	Software data processing version	Version of software used for data processing (i.e., creation of the analysis data set(s))	Free text	Manual entry
F3.8.2	Characteristics data processing tailored to data source	Study variables that need to be defined with a specific procedure (e.g., using data banks that are specific to this data source)	Free text	Manual entry
F3.9	Software data analysis	Name of software used for data analysis	Free text	Manual entry
F3.9.1	Software data analysis version	Version of software used for data analysis	Free text	Manual entry
F3.10	Data source strengths and limitations for this study	Description <i>a priori</i> of the strengths and limitations of this data source to address this research question	Free text	Manual entry
F3.10.1	Data characterisation results of this data source	·	As in F5.8	Automatic copy from F5.8
F3.10.2	Fitness-for-purpose of the data source	Description of the strengths and limitations of this data source to address this research question <i>a posteriori</i> : based on the results of the quality checks	Free text	Manual entry
F3.11	Study results of the data source	Results for this data source	As in F6	Automatic copy from F6
F3.11.1	Comments on the study results of the data source	Comments on the results for this data source	Free text	Manual entry
	List of key study variables of this	List of the names of the key variables (outcome, exposure, selection criteria, covariates,) derived from the data source in this study	Free text	Manual entry
F3.12	study			
F3.12.1	Operationalisation of the study variable	How the study variable was derived from this data source	Free text	Manual entry
F3.12.2	Validity of the study variable	Comments on variable validity, for instance if validation studies were conducted	Free text	Manual entry
F3.12.3	Comments to support interpretation of the study variable	Comments on the interpretation of the variable (for instance, if an outcome is expected only to be captured in severe cases, or if the reimbursement of a medicine is restricted to some age categories,)	Free text	Manual entry

Metadata category: Study - mappings to CDM
\* This is envisioned to be updated on a study-by-study basis and may link to the EU PAS register

Var ID	Var name	Description	Standards	Entry
F1.1	Study ID	A persistent identifier for a study. This may be created by the catalogue maintainer on first entry of a study. It provides links across tables.		
F4.1	CDM mapping	Were data sources in the study ETL-d to a CDM?	No/yes	Manual entry
F4.2	CDM name	If yes, select the name of the CDM from the following list.	Should take values in D1.1	Manual entry
F4.3	CDM mapping version	The version of the CDM used	Free text	Manual entry
F4.4	CDM ETL	If available, list of ETL specification documents uploaded to the catalogue. These documents should describe the mapping of the data source to the CDM.	Link to document	Manual entry
F4.4.1	Data source ETL code	If available, the ETL code or scripts uploaded to the catalogue. These are the code or scripts that were used to transform data from the origin source to the CDM.	URL/uploaded documents	Manual entry

CDM = common data model; ETL = extract, transform, load; ID = identifier.

- Metadata category: Study data characterisation

  \* This is envisioned to be updated on a study-by-study basis and may link to the EU PAS register

  \* Data characterisation results will be presented in the catalogue in the form of a dashboard

Var ID	Var name	Description	Standards	Entry
F1.1	Study ID	A persistent identifier for a study. This may be created by the catalogue maintainer on first entry of a study. It provides links across tables.		
F5.1	Data characterisation conducted	Was a data characterisation or quality check process completed?	No/yes	Manual entry
F5.2	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	Manual entry
F5.3	Check conformance	Was a check of the conformance of data (i.e., data are in the correct format/syntax) completed?	No/yes	Manual entry
F5.4	Check completeness	Was a check of the completeness of data completed?	No/yes	Manual entry
F5.5	Check stability	Was a check of the stability of data (e.g., codes) over time completed?	No/yes	Manual entry
F5.6	Check logical consistency	Was a check of the logical consistency of data completed?	No/yes	Manual entry
F5.7	Data characterisation details	Provide a summary description of the data characterisation or quality check process.	Free text/URL	Manual entry
F5.8	Data characterisation results	Provide results of the data characterisation or quality checks, such as Sentinel Common Data Model level 1-4 checks. These can be provided in a single document or URL. Upload in a standard form is envisioned, to facilitate visualisation.	Uploaded/URL	Manual entry

Metadata category: Study - results
\* This is envisioned to be updated on a study-by-study basis and may link to the EU PAS register

Var ID	Var name	Description	Standards	Entry
F1.1	Study ID	A persistent identifier for a study. This may be created by the catalogue maintainer on first entry of a study. It provides links across tables.		
F6.1	Procedure data extraction	Upload or provide a link (e.g., GitHub) to the procedures, such as codes or scripts, used to extract data data to create the data source instance used in the study.	Uploaded/URL	Manual entry
F6.2	Procedure results generation	Upload or provide a link (e.g., GitHub) to the procedures, such as study scripts, used to generate the study results	Uploaded/URL	Manual entry
F6.3	Summary results	A brief summary of the results of the study on study completion (from abstract)	Free text	Manual entry
F6.4	Results tables	Results tables from the study uploaded to the catalogue. Upload in a standard form is envisioned, to facilitate visualisation.	Uploaded	Manual entry

Metadata category: Study - publications
\* This is envisioned to be updated on a study-by-study basis and may link to the EU PAS register

Var ID	Var name	Description	Standards	Entry
F1.1	Study ID	A persistent identifier for a study. This may be created by the catalogue maintainer on first entry of a study. It provides links acre tables.	oss	
F7.1	Study publications	Peer-reviewed papers reporting the study	AMA citation format	Manual entry. If a persistent Study ID is maintained between this catalogue and the EUPAS register, this may be automatically populated on creation of an entry to the EUPAS register
F7.2	Study report	A link to the study report, if publicly available online	URL	Manual entry. If a persistent Study ID is maintained between this catalogue and the EUPAS register, this may be automatically populated on creation of an entry to the EUPAS register
F7.3	Study, other information	A list of URLs to other relevant resources describing the study	URL	Manual entry. If a persistent Study ID is maintained between this catalogue and the EUPAS register, this may be automatically populated on creation of an entry to the EUPAS register

AMA = American Medical Association; ID = identifier.

Metadata category: Study - data sources

Following recommendations in the Good Practice Guide, this table indicates a separate section of the catalogue to record study-dependent entries of metadata variables from the Data source catalogue domain. Information collected in this section of the catalogue, for example, through an interoperability with the EU PAS register, could be used to update the entries in

i	study independent part of table) 31.1		A persistent identifier for a data source. This may be created by the		Entry  Copied from section B of the data source participating in the study, and	data source, C = data bank, D = C = network, F = study)  B, F
F8B1.1	31.2		•		•	B, F
F8B1.2	31.2	Data source name  Data source local	Name of data source used in European projects  If different from above, name of data		Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data	B, F
F8B1.2.1	31.3	name	source in the national language of the data source  Official acronym of the institution, if		source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data	B, F
F8B1.3	31.4	acronym  Data source type	applicable.  Type of data source. Select one or	Biobank/ administrative claims/ electronic	source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data	B, F
F8B1.4	31.4.1	Data source type,	more of the following:  If other, describe the type of data	Free text	source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data	B, F
F8B1.4.1 B	31.5	Description of	Summary description of the data	Free text/URL	source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data	B, F
F8B1.5	31.6	Data source	,	Select from list of countries, links to ISO 3166-	•	B, F
F8B1.6	31.6.1	Data source	Geographical regions that data	(https://www.iso.org/obp/ui/#search/code/) Select from list of regions, links to ISO 3166-	source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data	B, F
F8B1.6.1	31.7	regions  Care setting	source covers  Type of care setting(s) covered by	(https://www.iso.org/obp/ui/#search/code/)  General population/ primary care/ secondary	source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data	B, F
F8B1.7	31.7.1	Care setting, other	data source.  If 'other,' description of the setting	Free text	source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data	B, F
F8B1.7.1 B	31.8	Data bank population	Describe in text the overlap	Free text	source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data	B, F
F8B1.8 B	32.1	The state of the s		Should take values from A1.1	source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data	B, F
F8B2.1	20.0		catalogue as having (conditional) permission to access (an extract of) the data source		source participating in the study, and then further edited by the DAP in the study	
В	32.2	Governance details	If available, provide documents or webpages that describe the overall governance of the data source (governing data access or utilisation for research purposes by		Copied from section B of the data source participating in the study, and then further edited by the DAP in the study	B, F
F8B2.2 B	32.2.1		existing DAPs)  Is there a committee that determines access to the data source (policy data access,	No/yes	Copied from section B of the data source participating in the study, and then further edited by the DAP in the	B, F
=8B2.2.1 B	32.3	Policy data access	committee data access) that are already listed?  If available, provide documents or webpages that describe the policy	Link to documents/URL	study  Copied from section B of the data source participating in the study, and	B, F
=8B2.3	32.4	Informed consent	for access to the data source.  Is informed consent required for use of the data for research	Not required / Required for general use/	then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, A, F
F8B2.4 B	32.4.1		purposes?  If other, describe the conditions when informed consent is required.	intervention studies/ waiver/ other  Free text	then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, A, F
F8B2.4.1	32.5	Access to identifiable data		No/yes	then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, A, F
-8B2.5			are already listed as having access (for example, patient name/practitioner name/practice name)?		then further edited by the DAP in the study	
	32.5.1	Route to access to identifiable data	If yes above, what is the route to access or process this information? What permission is required?	Free text	Copied from section B of the data source participating in the study, and then further edited by the DAP in the study	B, A, F
_	32.6	Access to subject details	Can individual patients/practitioners/practices be contacted in the data source?	No/yes	Copied from section B of the data source participating in the study, and then further edited by the DAP in the study	B, A, F
	32.6.1	1 '	If yes above, what is the route to access this information? What permission is required?	Free text	Copied from section B of the data source participating in the study, and then further edited by the DAP in the study	B, A, F
_	32.7		Are external parties allowed to audit the data? For example, is it possible for an external party to audit the quality or validity of the	No/yes	Copied from section B of the data source participating in the study, and then further edited by the DAP in the study	B, A, F
F8B2.7	32.8	Approval for	data source?  Is the catalogue contributor able to publish results from the data source without interaction from an	No/yes	Copied from section B of the data source participating in the study, and then further edited by the DAP in the	B, A, F
F8B2.8	33.1	Data source qualification	external organization, such as approval of a protocol?  Has the data source successfully undergone a formal qualification	No/yes	study  Copied from section B of the data source participating in the study, and	B, F
F8B3.1	33.1.1	1 ·	process (e.g., from the EMA, or ISO or other certifications)?  If yes, describe the qualification(s)		then further edited by the DAP in the study  Copied from section B of the data	B, F
8B3.1.1	33.1.1	qualifications  Data banks	granted.  A list of the data banks that might	Takes values from C1.1	source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data	B, F
-8B4.1	34.2		be included in this data source  A list of the families of data banks	Hospital discharge records/ primary care	source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data	B, C, F
				medical records/ pharmacy dispensation records/ birth registry/ induced terminations	source participating in the study, and then further edited by the DAP in the study	
				emergency care discharge records/ exemptions from copayment/ diagnostic tests or procedures reimbursement/ death registry/ cancer registry/ other disease registry/		
				vaccine registry/ biobank/ administrative claims/ spontaneous reporting of adverse drug reactions		
F8B4.2	34.2.1	Data bank families, other	If 'other' selected above, describe the type of data bank	Free text	Copied from section B of the data source participating in the study, and then further edited by the DAP in the	B, C, F
F8B4.2.1 B	34.3		Are data on geographic region available?	No/yes	Study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the	B, F
	34.4	Familylinkage	Is any linkage available in the data bank between any of the following persons?	Household/ mother-child/ father-child/ sibling	source participating in the study, and then further edited by the DAP in the	B, F
<sup>8</sup> 8B4.4 B	34.4.1		Is familial linkage created routinely or can linkage be performed on an ad-hoc basis?	Routine/ad hoc	Study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the	B, F
	34.4.2	Family linkage availability	Is familial linkage available for all of the data source population or a subset of individuals (or records)?	Full/subset	Copied from section B of the data source participating in the study, and then further edited by the DAP in the	B, F
	34.4.3	•	If a familial linkage is available for a subset of individuals (or records) only, provide a short description of the subset.	Free text	study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study	B, F
F8B4.4.3	34.5	Sociodemographic s included	Which of the following	None/ age/ sex/ gender/ ethnicity/ country of origin/ socioeconomic status/ marital status/ education level/ type of residency/ living in	Copied from section B of the data source participating in the study, and then further edited by the DAP in the study	B, F
F8B4.5	34.6	Lifestyle factors included	Which of the following lifestyle information is included? Select all	pharmaceutical copayment/ other  None/ tobacco use/ alcohol use/ frequency of	Copied from section B of the data	B, F
F8B4.6	34.7	Diagnosis codes	that apply.  Are diagnostic codes included?		source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data	B, F
F8B4.7	34.7.1	Diagnosis code	If yes, what vocabulary is used?	ICPC/ ICD9/ ICD10/ ICD1/ Read/	source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data	B, F
F8B4.7.1 B	34.7.2	vocabulary  Diagnosis code not coded	Select from the following:  If Not coded (Free text), approximately what percentage of	` '	then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, F
F8B4.7.2 B	34.7.3	Diagnosis, other	records are not coded?	Free text	then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, F
F8B4.7.3	34.8	Hospital admission	the form of diagnostic codes?  Is information on hospital admission and/or hospital	No/yes	then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, F
F8B4.8	34.8.1	ICU admission	discharge available?  Is information on intensive care unit admission available?		then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, F
F8B4.8.1	34.9	Cause of death	Is cause of death available?	No/yes	then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, F
F8B4.9	34.9.1	Cause of death vocabulary	If yes, what vocabulary is used? Select from the following:	ICPC/ ICD9/ ICD10/ ICD1/ Read/ SNOMED/ SNOMED CT/ MedDRA/ OPCS/		B, F
F8B4.9.1 B	34.9.2	Cause of death not coded	If Not coded (Free text), approximately what percentage of	CCS/ EDC/ Not coded (Free text)/ Other Unit: %, not applicable	then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, F
F8B4.9.2 B	34.9.3	Cause of death code, other	records are not coded?  If 'other,' what vocabulary is used?		then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, F
F8B4.9.3	34.10	Rare diseases	Are rare diseases (<1 in 2000 people) captured?		then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, F
F8B4.10 <b>B</b>	34.11	Prescriptions included		No/yes	then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, F
F8B4.11 B	34.11.1	Prescriptions vocabulary		ATC/ RxNorm/ EphMRA/ ALT/ Drug Bank/ Not coded (Free text)/ Other	then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, F
F8B4.11.1 B	34.11.2	Prescriptions not	If Not coded (Free text), approximately what percentage of	l '	then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, F
F8B4.11.2 B	34.11.3	Prescriptions vocabulary, other	records are not coded?	Free text	then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, F
F8B4.11.1 B	34.12	Dispensings included	Is information on dispensing of medications included?	No/yes	then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, F
F8B4.12 B	34.12.1	Dispensings vocabulary		ATC/ RxNorm/ EphMRA/ ALT/ DrugBank/	then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, F
F8B4.12.1 B	34.12.2	,	If Not coded (Free text), approximately what percentage of		then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, F
F8B4.12.2 B	34.12.3	Dispensings vocabulary, other	records are not coded?	Free text	then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, F
F8B4.12.3 B	34.13	Product	Is product information available? Select all items that apply.	Brand name/ batch number/ formulation/	then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, F
F8B4.13 B	34.13.1	Product information, product vocabulary	If product information is included, what vocabulary is used to describe	ART 57/ IFA GmbH/ EQDM/ SPN/ MTHSPL/	then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, F
F8B4.13.1 B	34.13.2	ľ	the product?  If 'other,' what vocabulary is used?	Free text	then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, F
F8B4.13.2 B	34.13.3	Product information, substance vocabulary	included, what vocabulary is used to	ART 57/ IFA GmbH/ EQDM/ SPN/ MTHSPL/	source participating in the study, and	B, F
F8B4.13.1 B	34.13.4	Substance vocabulary, other	describe the substance?  If 'other,' what vocabulary is used?	Free text	then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the	B, F
F8B4.13.4 B	34.13.5	Other medicines	Is other information on medicines or products included?	No/yes	then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, F
F8B4.13. <b>5</b> B	34.13.6	Other medicines information details	If yes to the above, select all the items that apply.	Dose/ dosage regime/ route of	then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, F
F8B4.13.€ <b>E</b>	34.14	АТМР	Is information on advanced therapy medicinal products included?		then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, F
F8B4.14	34.15	Contraception	Is information on contraceptives included?	No/yes	then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, F
F8B4.15	34.15.1	Emergency contraception	If yes, is information on emergency contraceptives included?		then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, F
F8B4.15.1 B	34.16	Indication for use	If medicines information is captured, is the indication for use recorded?	No/yes/not applicable	then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the	B, F
F8B4.16 B	34.16.1	Indication vocabulary	recorded?  If yes, what vocabulary is used?  Select from the following:	ICPC/ ICD9/ ICD10/ ICD1/ Read/ SNOMED/ SNOMED CT/ MedDRA/ OPCS/	then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the	B, F
F8B4.16.1 B	34.16.2	Indication not coded	If Not coded (Free text), approximately what percentage of	CCS/ EDC/ Not coded (Free text)/ Other Unit: %, not applicable	then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the	B, F
F8B4.16.2 B	34.16.3		records are not coded?  If 'other,' what vocabulary is used?		then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, F
F8B4.16.5 B	34.17	Administration	Is information on the administration of vaccines included?		then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, F
F8B4.17 B	34.17.1	Administration other injectable	Is information on the administration of other injectable medicines	No/yes	then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, F
F8B4.17.1 B	34.18	medicines  Medical devices	included?  Is information on medical devices included?		then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, F
1	34.19	Procedures included	Is information on procedures (e.g., diagnostic tests, therapeutic,		then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, F
		Procedures	surgical) included?  If yes, what vocabulary is used?  Select from the following:	ICPC/ ICD9/ ICD10/ ICD1/ Read/ SNOMED/ SNOMED CT/ MedDRA/ OPCS/	then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, F
-8B4.19	34.19.1	vocabulary	g.	CCS/ EDC/ Not coded (Free text)/ Other	then further edited by the DAP in the	1
F8B4.19 B F8B4.19.1	34.19.1	Procedures not coded	If Not coded (Free text), approximately what percentage of		Study  Copied from section B of the data source participating in the study, and	B, F
F8B4.19.2 F8B4.19.2		Procedures not	If Not coded (Free text), approximately what percentage of records are not coded?	Unit: %, not applicable  Free text	Copied from section B of the data	B, F



F8B4.19.		·	Select from the following:	SNOMED/ SNOMED CT/ MedDRA/ OPCS/ CCS/ EDC/ Not coded (Free text)/ Other	source participating in the study, and then further edited by the DAP in the study	B, F
	B4.19.6		If Not coded (Free text), approximately what percentage of records are not coded?	Unit: %, not applicable	·	B, F
F8B4.19.6	B4.19.7	Procedure results vocabulary, other	If 'other,' what vocabulary is used?	Free text	study  Copied from section B of the data source participating in the study, and	B, F
F8B4.19.7	B4.20	Clinical measures included	Is information on clinical measures included (e.g., BMI, blood	No/yes	then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, F
F8B4.20	B4.21	Healthcare centre	pressure)?		then further edited by the DAP in the study	B, F
F8B4.21	54.21		centre (e.g., pharmacy, general practice, hospital) available?	,	source participating in the study, and then further edited by the DAP in the study	5,1
	B4.21.1		Is information on the person providing healthcare (e.g., physician, pharmacist, specialist) available?		source participating in the study, and then further edited by the DAP in the	B, F
F8B4.21.1	B4.22	Genetic data		No/yes	Study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the	B, F
F8B4.22	B4.22.1	Genetic data vocabulary	, ,	OGG/ FG/ GO/ EGO/ SOPHARM/ PHARE/	study  Copied from section B of the data source participating in the study, and	B, F
F8B4.22.1	B4.22.2	Genetic data	Č		then further edited by the DAP in the study  Copied from section B of the data	B, F
F8B4.22.2		vocabulary, other			source participating in the study, and then further edited by the DAP in the study	
	B4.22.3	Genetic data summary	A short summary of how genetic information is captured in the data source.		source participating in the study, and then further edited by the DAP in the	B, F
F8B4.22.(	B4.23	Biomarker data	Is biomarker information available?	No/yes	Study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the	B, F
F8B4.23	B4.23.1	Biomarker data vocabulary	If yes, what vocabulary is used? Select from the following:	BMO/ SMASH/ FOBI/ other	study  Copied from section B of the data source participating in the study, and	B, F
F8B4.23.1	, B4.23.2	Biomarker data	Č		then further edited by the DAP in the study  Copied from section B of the data	B, F
F8B4.23.2		vocabulary, other	in outsi, mac recapulary to accu.		source participating in the study, and then further edited by the DAP in the study	
	B4.23.3	Biomarker data summary	A short summary of how biomarker information is captured in the data source.		source participating in the study, and then further edited by the DAP in the	B, F
F8B4.23.3	B4.24	Patient-generated data	(e.g., from wearable devices)	No/yes	source participating in the study, and	B, F
F8B4.24	B4.24.1			Free text	then further edited by the DAP in the study  Copied from section B of the data	B, F
F8B4.24.1	1	·	generated information (e.g., from wearable devices) is captured in the data source.		source participating in the study, and then further edited by the DAP in the study	
	B4.25	•	available? Select all that apply.	HRQOL/ WHOQOL/ EQ5D/ 15D/ SF-36/ SF- 6D/ HUI/ other	Copied from section B of the data source participating in the study, and then further edited by the DAP in the study	B, F
F8B4.25	B4.25.1	Quality of life, other	If other, specify additional quality of life measures.		Copied from section B of the data source participating in the study, and then further edited by the DAP in the	B, F
F8B4.25.1	B4.26	Costs	Is information on costs of healthcare available?	No/yes	study  Copied from section B of the data source participating in the study, and	B, F
F8B4.26	B4.27.1	Use of NLP	Is natural language processing	No/yes/not applicable	then further edited by the DAP in the study  Copied from section B of the data	B, F
F8B4.27.1			used to process free text information into standardised information?		source participating in the study, and then further edited by the DAP in the study	
	B4.27.2	Details of NLP	used, provide a summary description of how natural		source participating in the study, and then further edited by the DAP in the	B, F
F8B4.27.2	B4.27.3	Deidentified text	lang uage processing is used.  Are procedures in place to de- identify or remove personal information from free text?	No/yes/not applicable	Study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the	B, F
F8B4.27.3	B4.27	Free text		No/yes	study  Copied from section B of the data source participating in the study, and	B, F
F8B4.27	B5.1	Linkage description	Provide a high-level description of		then further edited by the DAP in the study	B, F
	B3. 1		the linkages that are currently available between data banks in the data source (max 100 words).		source participating in the study, and then further edited by the DAP in the study	ъ, г
F8B5.1	B5.2	Linkage strategy		•	Copied from section B of the data source participating in the study, and	B, F
F8B5.2	B5.2.1	Linkage variable	data bank.  If a single variable (or linkage key)		then further edited by the DAP in the study  Copied from section B of the data	B, C, F
			is used to link a data bank to others, a name and description of the variable is provided.		source participating in the study, and then further edited by the DAP in the study	
F8B5.2.1	B5.2.2	Linkage variable unique	If a single variable is used to link a data bank to others, is the variable a	•	source participating in the study, and	B, C, F
F8B5.2.2	B5.3	Linkage		Free text	then further edited by the DAP in the study  Copied from section B of the data	B, F
50550		completeness	the completeness of linkages that are currently available between data banks in the data source (max 100 words).		source participating in the study, and then further edited by the DAP in the study	
F8B5.3	B6.1	Population size	Total number of unique individuals with records captured in the data source (most recent count). In the		Copied from section B of the data source participating in the study, and then further edited by the DAP in the	B, F
F8B6.1			catalogue, this will accommodate counts per year.		study	
	B6.1.1	Population size active	currently registered individuals with records captured in the data source		Copied from section B of the data source participating in the study, and then further edited by the DAP in the	B, F
			(most recent count). In the catalogue, this will accommodate counts per year.		study	
F8B6.1.1	B6.2		records of biological samples		source participating in the study, and	B, F
			(e.g., blood, urine) (most recent count). In the catalogue, this will accommodate counts per year.		then further edited by the DAP in the study	
F8B6.2	B6.3	Median observation time	Median time for which unique individuals with records captured in the data source are observable		Copied from section B of the data source participating in the study, and then further edited by the DAP in the	B, F
F8B6.3	B6.3.1	Median observation time	(most recent count).	Unit: years	study  Copied from section B of the data source participating in the study, and	B, F
F8B6.3.1		active	individuals with records captured in the data source are observable (most recent count).		then further edited by the DAP in the study	
	B6.4	Population size by age	with records captured in the data	Numeric, for each of the following categories: newborn infants (0 to 27 days), infants and toddlers (28 days to 23 months), children (2 to	source participating in the study, and	B, F
			stratified by ag e	11 years), adolescents (12 to 17 years), adults (18 to 45 years), adults (46 to 64 years), adults (65 to 75 years), adults (76	study	
F8B6.4	B6.4.1	Population size active		years and over)  Numeric, for each of the following categories:	Copied from section B of the data	B, F
		•	currently registered individuals with records captured in the data source (most recent count), stratified by	newborn infants (0 to 27 days), infants and toddlers (28 days to 23 months), children (2 to 11 years), adolescents (12 to 17 years),	source participating in the study, and	
				adults (18 to 45 years), adults (46 to 64 years), adults (65 to 75 years), adults (76 years and over)		
F8B6.4.1	B6.5	_	population (e.g., in the		source participating in the study, and	B, F
			geographical population that the data source covers, based on external estimates, e.g., census)		then further edited by the DAP in the study	
F8B6.5	B6.5.1	_	Median age of individuals within data source		Copied from section B of the data source participating in the study, and then further edited by the DAP in the	B, F
	B6.6	Proportion female in the underlying	Proportion of females in the underlying population (based on	Unit: %	then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and	B, F
	Ī	GI IGO I VITIÚ	underlying population (based on external estimates, e.g., census)		source participating in the study, and then further edited by the DAP in the study	
F8B6.6	B6.6.1	population	Proportion of females in the data	Unit: %	•	B, F
F8B6.6		population  Proportion female	Proportion of females in the data source	Unit: %	•	B, F
F8B6.6 F8B6.6.1		Proportion female data source  Proportion ethnicity in the underlying		Unit: % Unit: %, per ethnicity group	Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the	B, F
F8B6.6.1 F8B6.7		Proportion female data source  Proportion ethnicity in the underlying population  Proportion ethnicity data	Proportion of people per ethnicity in the underlying population (based	Unit: %  Unit: %, per ethnicity group  Unit: %, per ethnicity group	Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study	
F8B6.6.1 F8B6.7	B6.7	Proportion female data source  Proportion ethnicity in the underlying population  Proportion	Proportion of people per ethnicity in the underlying population (based on external estimates, e.g., census)  Proportion of people per ethnicity in the data source  Has One or more data banks of the	Unit: %  Unit: %, per ethnicity group  Unit: %, per ethnicity group	Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study in the study, and then further edited by the DAP in the study  Copied from section B of the data	B, F
F8B6.6.1 F8B6.7 F8B6.7.1	B6.7.1 B6.7.1	Proportion female data source  Proportion ethnicity in the underlying population  Proportion ethnicity data source  Data source ETL	Proportion of people per ethnicity in the underlying population (based on external estimates, e.g., census)  Proportion of people per ethnicity in the data source  Has One or more data banks of the data source been ETL-d to a common data model?	Unit: %  Unit: %, per ethnicity group  Unit: %, per ethnicity group  No/yes	Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study	B, F  B, F
F8B6.6 F8B6.6.1 F8B6.7.1	B6.7.1	Proportion female data source  Proportion ethnicity in the underlying population  Proportion ethnicity data source  Data source ETL	Proportion of people per ethnicity in the underlying population (based on external estimates, e.g., census)  Proportion of people per ethnicity in the data source  Has One or more data banks of the data source been ETL-d to a	Unit: %  Unit: %, per ethnicity group  Unit: %, per ethnicity group  No/yes  Should take values within D1.1	Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study	B, F
F8B6.6.1 F8B6.7 F8B6.7.1 F8B7.1	B6.7.1 B6.7.1	Proportion female data source  Proportion ethnicity in the underlying population  Proportion ethnicity data source  Data source ETL  Data source ETL  Data source ETL	Proportion of people per ethnicity in the underlying population (based on external estimates, e.g., census)  Proportion of people per ethnicity in the data source  Has One or more data banks of the data source been ETL-d to a common data model?  Name of CDM(s) to which the data	Unit: %  Unit: %, per ethnicity group  Unit: %, per ethnicity group  No/yes  Should take values within D1.1	Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the	B, F  B, F
F8B6.6.1 F8B6.7 F8B6.7.1 F8B7.1	B6.7.1 B7.1 B7.2	Proportion female data source  Proportion ethnicity in the underlying population  Proportion ethnicity data source  Data source ETL  CDM  Data source ETL  CDM version	Proportion of people per ethnicity in the underlying population (based on external estimates, e.g., census)  Proportion of people per ethnicity in the data source  Has One or more data banks of the data source been ETL-d to a common data model?  Name of CDM(s) to which the data source has been ETL-d  Version(s) of CDM(s) to which the data source has been ETL-d	Unit: %  Unit: %, per ethnicity group  Unit: %, per ethnicity group  No/yes  Should take values within D1.1  Free text  URL/uploaded documents	Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study	B, F  B, F  B, F
F8B6.6.1 F8B6.7 F8B6.7.1 F8B7.1	B6.7.1 B7.1 B7.2	Proportion female data source  Proportion ethnicity in the underlying population  Proportion ethnicity data source  Data source ETL  CDM  Data source ETL  CDM version	Proportion of people per ethnicity in the underlying population (based on external estimates, e.g., census)  Proportion of people per ethnicity in the data source  Has One or more data banks of the data source been ETL-d to a common data model?  Name of CDM(s) to which the data source has been ETL-d  Version(s) of CDM(s) to which the data source has been ETL-d	Unit: %  Unit: %, per ethnicity group  Unit: %, per ethnicity group  No/yes  Should take values within D1.1  Free text  URL/uploaded documents	Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data	B, F  B, F  B, F
F8B6.6.1 F8B6.7 F8B6.7.1 F8B7.1 F8B7.2 F8B7.3	B6.7.1 B7.1 B7.2	Proportion female data source  Proportion ethnicity in the underlying population  Proportion ethnicity data source  Data source ETL  CDM  Data source ETL  CDM version  Data source ETL  CDM version	Proportion of people per ethnicity in the underlying population (based on external estimates, e.g., census)  Proportion of people per ethnicity in the data source  Has One or more data banks of the data source been ETL-d to a common data model?  Name of CDM(s) to which the data source has been ETL-d  Version(s) of CDM(s) to which the data source has been ETL-d  If available, list of ETL specification documents uploaded to the catalogue. These documents describe the mapping of the data source to the CDM.  If available, the ETL code or scripts uploaded to the catalogue. These	Unit: %  Unit: %, per ethnicity group  Unit: %, per ethnicity group  No/yes  Should take values within D1.1  Free text  URL/uploaded documents  URL/uploaded documents	Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study	B, F  B, F  B, F
F8B6.6.1 F8B6.7 F8B6.7.1 F8B7.1 F8B7.2 F8B7.3	B6.7.1  B7.1  B7.3	Proportion female data source  Proportion ethnicity in the underlying population  Proportion ethnicity data source  Data source ETL  CDM  Data source ETL  CDM version  Data source ETL  CDM version	Proportion of people per ethnicity in the underlying population (based on external estimates, e.g., census)  Proportion of people per ethnicity in the data source  Has One or more data banks of the data source been ETL-d to a common data model?  Name of CDM(s) to which the data source has been ETL-d  Version(s) of CDM(s) to which the data source has been ETL-d  If available, list of ETL specification documents uploaded to the catalogue. These documents describe the mapping of the data source to the CDM.	Unit: %, per ethnicity group  Unit: %, per ethnicity group  No/yes  Should take values within D1.1  Free text  URL/uploaded documents  URL/uploaded documents	Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study	B, F  B, F  B, F  B, F
F8B6.6.1 F8B6.7.1 F8B7.1 F8B7.2 F8B7.3	B6.7.1  B7.1  B7.3	Proportion female data source  Proportion ethnicity in the underlying population  Proportion ethnicity data source  Data source ETL  CDM  Data source ETL  CDM version  Data source ETL  CDM version  Data source ETL  CDM version	Proportion of people per ethnicity in the underlying population (based on external estimates, e.g., census)  Proportion of people per ethnicity in the data source  Has One or more data banks of the data source been ETL-d to a common data model?  Name of CDM(s) to which the data source has been ETL-d  Version(s) of CDM(s) to which the data source has been ETL-d  If available, list of ETL specification documents uploaded to the catalogue. These documents describe the mapping of the data source to the CDM.  If available, the ETL code or scripts uploaded to the catalogue. These are the code or scripts that were used to transform data from the original source to the CDM.  A list of IDs of studies that have been conducted using the data	Unit: %  Unit: %, per ethnicity group  Unit: %, per ethnicity group  No/yes  Should take values within D1.1  Free text  URL/uploaded documents  URL/uploaded documents	Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study	B, F  B, F  B, F  B, F
F8B6.6.1 F8B6.7.1 F8B7.1 F8B7.3 F8B7.4 F8B7.4.1	B6.7.1  B7.1  B7.3  B7.4	Proportion female data source  Proportion ethnicity in the underlying population  Proportion ethnicity data source  Data source ETL  CDM  Data source ETL  CDM version  Data source ETL  CDM version  Data source ETL  CDM version	Proportion of people per ethnicity in the underlying population (based on external estimates, e.g., census)  Proportion of people per ethnicity in the data source  Has One or more data banks of the data source been ETL-d to a common data model?  Name of CDM(s) to which the data source has been ETL-d  Version(s) of CDM(s) to which the data source has been ETL-d  If available, list of ETL specification documents uploaded to the catalog ue. These documents describe the mapping of the data source to the CDM.  If available, the ETL code or scripts uploaded to the catalogue. These are the code or scripts that were used to transform data from the original source to the CDM.  A list of IDs of studies that have been conducted using the data source that are recorded in the catalogue. List the types of regulatory studies	Unit: %, per ethnicity group  Unit: %, per ethnicity group  No/yes  Should take values within D1.1  Free text  URL/uploaded documents  URL/uploaded documents  Should take values in F1.1	Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study	B, F  B, F  B, F  B, F  B, F
F8B6.6.1 F8B6.7.1 F8B7.1 F8B7.2 F8B7.3 F8B7.4	B6.7 B6.7.1 B7.1 B7.3 B7.4 B7.4.1	Proportion female data source  Proportion ethnicity in the underlying population  Proportion ethnicity data source  Data source ETL CDM  Data source ETL CDM version  Data source ETL code  Data source ETL specifications	Proportion of people per ethnicity in the underlying population (based on external estimates, e.g., census)  Proportion of people per ethnicity in the data source  Has One or more data banks of the data source been ETL-d to a common data model?  Name of CDM(s) to which the data source has been ETL-d  Version(s) of CDM(s) to which the data source has been ETL-d  If available, list of ETL specification documents uploaded to the catalogue. These documents describe the mapping of the data source to the CDM.  If available, the ETL code or scripts uploaded to the catalogue. These are the code or scripts that were used to transform data from the original source to the CDM.  A list of IDs of studies that have been conducted using the data source that are recorded in the catalogue  List the types of regulatory studies that the data source has been used for (e.g., PASS, PAES,).	Unit: %, per ethnicity group  Unit: %, per ethnicity group  No/yes  Should take values within D1.1  Free text  URL/uploaded documents  URL/uploaded documents  Should take values in F1.1  Should take values in F2.4 - study - protocol	Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study	B, F  B, F  B, F  B, F  B, F  B, F
F8B6.6.1 F8B6.7.1 F8B7.1 F8B7.2 F8B7.4 F8B8.1	B6.7.1  B7.1  B7.3  B7.4  B8.1	Proportion female data source  Proportion ethnicity in the underlying population  Proportion ethnicity data source  Data source ETL CDM  Data source ETL CDM version  Data source ETL code  Data source ETL specifications  Data source ETL specifications	Proportion of people per ethnicity in the underlying population (based on external estimates, e.g., census)  Proportion of people per ethnicity in the data source  Has One or more data banks of the data source been ETL-d to a common data model?  Name of CDM(s) to which the data source has been ETL-d  Version(s) of CDM(s) to which the data source has been ETL-d  If available, list of ETL specification documents uploaded to the catalogue. These documents describe the mapping of the data source to the CDM.  If available, the ETL code or scripts uploaded to the catalogue. These are the code or scripts that were used to transform data from the original source to the CDM.  A list of IDs of studies that have been conducted using the data source that are recorded in the catalogue  List the types of regulatory studies that the data source has been used for (e.g., PASS, PAES,).	Unit: %, per ethnicity group  Unit: %, per ethnicity group  No/yes  Should take values within D1.1  Free text  URL/uploaded documents  URL/uploaded documents  Should take values in F1.1  Should take values in F2.4 - study - protocol  URL	Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study	B, F  B, F  B, F  B, F  B, F
F8B6.6 F8B6.6.1 F8B6.7.1 F8B7.1 F8B7.2 F8B7.4 F8B8.1	B6.7 B6.7.1 B7.1 B7.3 B7.4 B7.4.1	Proportion female data source  Proportion ethnicity in the underlying population  Proportion ethnicity data source  Data source ETL CDM  Data source ETL CDM version  Data source ETL specifications  Data source ETL code  Data source ETL specifications	Proportion of people per ethnicity in the underlying population (based on external estimates, e.g., census)  Proportion of people per ethnicity in the data source  Has One or more data banks of the data source been ETL-d to a common data model?  Name of CDM(s) to which the data source has been ETL-d  Version(s) of CDM(s) to which the data source has been ETL-d  If available, list of ETL specification documents uploaded to the catalogue. These documents describe the mapping of the data source to the CDM.  If available, the ETL code or scripts uploaded to the catalogue. These are the code or scripts that were used to transform data from the original source to the CDM.  A list of IDs of studies that have been conducted using the data source that are recorded in the catalogue  List the types of regulatory studies that the data source has been used for (e.g., PASS, PAES,).  If applicable, a dedicated website for the data source	Unit: %, per ethnicity group  Unit: %, per ethnicity group  No/yes  Should take values within D1.1  Free text  URL/uploaded documents  URL/uploaded documents  Should take values in F1.1  Should take values in F2.4 - study - protocol  URL  Allow individual AMA format citations / URL to list of publications.	Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study	B, F  B, F  B, F  B, F  B, F  B, F
F8B6.6.1 F8B6.7.1 F8B7.1 F8B7.3 F8B7.4 F8B8.1 F8B8.1	B6.7.1  B7.1  B7.3  B7.4  B8.1  B8.1	Proportion female data source  Proportion ethnicity in the underlying population  Proportion ethnicity data source  Data source ETL CDM  Data source ETL CDM version  Data source ETL specifications  Data source ETL code  Data source ETL specifications	Proportion of people per ethnicity in the underlying population (based on external estimates, e.g., census)  Proportion of people per ethnicity in the data source  Has One or more data banks of the data source been ETL-d to a common data model?  Name of CDM(s) to which the data source has been ETL-d  Version(s) of CDM(s) to which the data source has been ETL-d  If available, list of ETL specification documents uploaded to the catalogue. These documents describe the mapping of the data source to the CDM.  If available, the ETL code or scripts uploaded to the catalogue. These are the code or scripts that were used to transform data from the original source to the CDM.  A list of IDs of studies that have been conducted using the data source that are recorded in the catalogue  List the types of regulatory studies that the data source has been used for (e.g., PASS, PAES,).  If applicable, a dedicated website for the data source	Unit: %, per ethnicity group  Unit: %, per ethnicity group  No/yes  Should take values within D1.1  Free text  URL/uploaded documents  URL/uploaded documents  Should take values in F1.1  Should take values in F2.4 - study - protocol  URL  Allow individual AMA format citations / URL to list of publications.	Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study  Copied from section B of the data source participating in the study, and then further edited by the DAP in the study	B, F  B, F  B, F  B, F  B, F  B, F



Metadata category: Study - data banks
Following recommendations in the Good Practice Guide, this table indicates a separate section of the catalogue to record study-dependent entries of metadata variables from the Data bank catalogue domain. Information collected in this section of the catalogue, for example, through an interoperability with the EU PAS register, could be used to update the

-	of table)	Data bank ID	A persistent identifier for a data bank. This may be created by the catalogue maintainer on first entry of a data bank. It provides links across tables			source, C = data bank, D = CDM, E = network, F = study
F9C1.2	C1.2 C1.2.1	Data bank name  Data bank local name	tables.  Name of data bank used in European projects  If different from above, name of data bank in the national language of the data source	Free text	Manual entry  Manual entry	C, F C, F
	C1.3 C1.4	Data bank acronym  Description of underlying population	If applicable Provide a summary description of the underlying population (maximum 100 words) or	Free text Free text/URL	Manual entry Manual entry	C, F C, F
F9C1.4 F9C1.5	C1.5	Data bank countries	URL to a description  Countries where data originate (1 or more)	Select from list of countries, links to ISO 3166-1 country codes (https://www.iso.org/obp/ui/#search/code/)	Manual entry	C, F
F9C1.5.1	C1.5.1				Manual entry  Manual entry	C, F
F9C1.6	C1.6.1	of population entry  Causes Event triggering	to enter the underlying population of the data bank.  If other, specify the causes /event determining	obtained/ insurance coverage start/ disease diagnosis/ treatment started/ practice registration/ other Free text	Manual entry	C, F
F9C1.6.1	C1.7	of population entry other  Causes of population exit	population exit of entry to the underlying population.  Select the possible causes / /event determining population exit for a person to leave the	Death/ emigration/ insurance coverage end/ practice	Manual entry	C, F
F9C1.7 F9C1.7.1	C1.7.1		underlying population of the data bank  If other, specify the causes / /event determining population exit of exit from the underlying population.	deregistration/ loss to follow up/ other / End of treatment Free text	Manual entry	C, F
	C1.8	Population age groups	Which population age groups are captured in the data bank? Select all that are relevant.	Numeric, for each of the following categories: newborn infants (0 to 27 days), infants and toddlers (28 days to 23 months), children (2 to 11 years), adolescents (12 to 17 years),	Manual entry	C, F
				adults (18 to 45 years), adults (46 to 64 years), adults (65 to 75 years), adults (76 years and over)		
F9C1.9	C1.9 C1.10	Population pregnancy and neon  Disease subpopulations	Does the data bank collect information on pregnant women and/or neonatal subpopulation?  Does the data bank collect information on a	No/yes No/yes	Manual entry  Manual entry	C, F
F9C1.10 F9C1.10. <sup>4</sup>		Disease subpopulations details  Population coverage	specific disease subpopulation c)?  If yes, which disease subpopulations does the data bank collect information on?  Are there any people from the underlying	Free text No/yes	Manual entry  Manual entry	C, F
		i opananon oo o ago	population that the data bank covers whose data are not collected in the data bank (e.g., people without a national insurance number, people who are registered for private care)?		a.iaa. o.u.y	
F9C1.11.1	C1.11.1 C1.11.2	Population coverage details  Population coverage,		Free text Unit: %	Manual entry  Manual entry	C, F
F9C1.12	C1.12	Time span - first collection Time span - last collection	is covered by the data bank?  On what date did records first start entering the data bank?  If data collection in the data bank has ceased, on what date did new records last enter the data	DDMMYYYY	Manual entry  Manual entry	C
F9C1.14	C1.14 C1.14.1	Care setting  Care setting, other	bank?  Type of care setting(s) covered by data bank  If 'other,' description of the setting of care.	General population/ primary care/ secondary care/ tertiary care/ other Free text	Manual entry  Manual entry	C
F9C1.14.1	C2.1	DAPs		Should take values from A1.1	Automatically populated when a contributor enters A2.3 Ins-data sources and data banks-Is DAP as yes and a data bank with	С
	C2.2	Data controller	The name of the institution or organisation that is responsible for governance of the data bank	Free text	corresponding Data bank ID is selected  Manual entry	С
F9C2.2	C2.3	Governance details	If available, provide documents or webpages that describe the overall governance of the data bank (governing data access or utilisation for research purposes by existing DAPs)	Link to documents/URL	Manual entry	С
F9C2.3 F9C2.3.1	C2.3.1	Committee data access Policy data access	Is there a committee that determines access to the data source by the DAPs that are already listed?  If available, provide documents or webpages	No/yes Link to documents/URL	Manual entry  Manual entry	C
F9C2.4	C2.4 C2.5	Policy data access  Informed consent	If available, provide documents or webpages that describe the policy for access to the data bank.  Is informed consent required for use of the data for research purposes?		Manual entry  Manual entry	C, A
F9C2.5.1	C2.5.1 C2.6	Informed consent other  Access to identifiable	If other, describe the conditions when informed consent is required.  Can identifiable data be accessed in the data back (including potion) for actions.		Manual entry  Manual entry	C, A C, A
F9C2.6 F9C2.6.1	C2.6.1	data  Route to access to identifiable data	bank (including patient/practitioner name/practice name)?  If yes above, what is the route to access this information? What permission is required?	No/yes	Manual entry	C, A
	C2.7.1	Access to subject details  Route to access to subject details	Can individual patients/practitioners/practices be contacted in the data bank?  If yes above, what is the route to access this information? What permission is required?	No/yes Free text	Manual entry  Manual entry	C, A C, A
F9C2.7.1	C2.8	details  Audit possibility	· ·	No/yes	Manual entry	C, A
F9C2.8 F9C2.9	C2.9	Approval for publication	Is the catalogue contributor able to publish results from the data bank without interaction from an external organization, such as approval of a protocol?		This is entered manually per institution that makes an entry for the data source in the catalogue	
F9C2.10	C2.10 C2.10.1	Third-party access Third-party access conditions	Can (an extract of) the data bank be accessed with permission by a third party?  If yes above, describe the conditions under which third-party access may be granted	No/yes Free text	Manual entry  Manual entry	С
F9C2.10. <sup>2</sup> F9C2.11	C2.11	Non-EU EEA access	(another organisation that is not a data originator or a DAP)	No/yes	Manual entry	С
	<b>C2.11.1</b> C2.12	Non–EU EEA access conditions  Standard operating procedures	If yes above, describe the conditions under which third-party access may be granted  Is there a standard operating procedure document that defines the processes and	No/yes No/yes	Manual entry  Manual entry	C
F9C2.12	C2.13	procedures  Biospecimen access	document that defines the processes and procedures for data capture and management?  If the data bank contains biospecimens (e.g., tissue samples), can these be retrieved?	No/yes	Manual entry	С
F9C2.13	C2.13.1	Biospecimen access conditions  Data bank qualification	If yes above, describe the conditions under which permission to retrieve biospecimens may be granted.  Has the data bank successfully undergone a	Free text No/yes	Manual entry  Manual entry	C
F9C3.1 F9C3.1.1	C3.1.1	Description of qualifications Originator	qualification process (e.g., from the EMA)?  If yes, describe the qualification(s) granted.  Name of the organisation that maintains the	Free text	Manual entry  Manual entry	C C
F9C4.1 F9C4.1.1	C4.1.1	Originator email contact  Type of organisation	collection of records.  Contact email address of the originator organization  Description of the type of organisation that is originator of the data bank.	Free text; must take form "prefix@domain"	Manual entry  Manual entry	С С
			originator of the data parit	payer/ network of primary care practices/ non-profit organisation/ pharmaceutical industry/ private organisation/ public health authority/ research centre/ statistical authority		
F9C4.2 F9C4.2.1	C4.2.1	Type of organisation, other	If other, description of the type of originator.	Free text	Manual entry	С
	C4.3	Description of data collection	Describe the process of collection and recording of data in the data bank. This could include the tools, such as surveys, used, or a description of the system that the originator uses to gather data and store it the data bank.	Free text	Manual entry	С
F9C4.3	C4.4	Reason data bank is sustained	Description of the reason why the data bank is sustained by the organisation (e.g., for surveillance, clinical purposes, financial or administrative purposes, research purposes).	Free text	Manual entry	С
F9C4.5	<b>C4.5</b> C4.6	Date established Finance source	Date that the data bank was first established.  Specify the main financial support sources for		Manual entry  Manual entry	C
			the data bank in the last 3 years. Select all that apply.	regional, or municipal public funding/ European public funding/ funding from industry or contract research/ funding from public-private partnership/ funds from patients organisations, charity and		
F9C4.6 F9C4.6.1	C4.6.1 <b>C5.1</b>	Finance source, other  Data bank family	Specify Which of the following families of data banks best describe this data bank?	foundations/ other  Free text  Hospital discharge records/ primary care medical records/ pharmacy	Manual entry Manual entry	C C
				dispensation records/ birth registry/ induced terminations registry/ congenital anomaly registry/ inhabitant registry/ registration with healthcare system/ outpatient visit		
				records/ emergency care discharge records/ exemptions from copayment/ diagnostic tests or procedures reimbursement/ death registry/ cancer registry/ other disease registry/ vaccine registry/ biobank/		
				administrative claims / spontaneous reporting of adverse drug reactions		
F9C5.1.1	C5.1.1 C5.2	Data bank family, other  Data bank prompt	If 'other,' describe the type of the data bank.  What prompts the creation of a record in the data bank? e.g., hospital discharge, specialist	Free text Free text	Manual entry  Manual entry	C
F9C5.2	C5.3	Data bank prompt	encounter, dispensation of a medicinal product, recording of a congenital anomaly  Describe any exceptions when the data bank	Free text	Manual entry	С
F9C5.4	C5.4	exception  Unit of observation	prompt would not lead to creation of a record.  Based on the prompt, what is the unit of observation of a record (e.g., person, prescription)?	Free text	Manual entry	С
F9C5.5	<b>C5.5</b> C6.1	Multiple entries  Data dictionary present	Can there be multiple entries for a single person in the data bank? For example, may a person contribute multiple records to the data bank?  Are a data dictionary and a data model	No/yes	Manual entry  Manual entry	С
F9C6.1	C6.1.1	Data dictionary present  Data dictionary  document	available?  If available, a list of data dictionary and data model documents is entered. The data dictionary contains the list of variables captured in the data bank, according to the data model,	Links to documents	Manual entry  Manual entry	С
F9C6.1.2	C6.1.2		with descriptions.  Number of separate tables within the data bank		Manual entry	С
F9C6.1.3	C6.1.4	Data dictionary item names  Data dictionary values	Data dictionary: inclusion of data item names  Data dictionary: inclusion of codes, value ranges, & measurement units	Yes, but not for all variables;	Manual entry  Manual entry	С
F9C6.1.4	C6.1.5	Data dictionary algorithms	Data dictionary: inclusion of formulae & algorithms used for derived variables	No Yes, for all derived variables; Yes, but not for all derived variables; No; Not required as source does not	Manual entry	C
	C6.1.6	Data dictionary language	Languages in which that the data bank dictionary is recorded	contain derived variables  List of languages linked to ISO 639 codes (https://www.iso.org/iso-639-language-codes.html)	Manual entry	С
F9C6.1.5			1	Links to documents	Manual entry	C C
F9C6.1.7	C6.1.7	Data dictionary summary  Data bank language	If available, a summary data dictionary or abridged version is entered  Languages in which that the records in the data bank are recorded		Manual entry	
F9C6.1.6 F9C6.1.7 F9C6.2	C6.1.7	, ,	abridged version is entered  Languages in which that the records in the data bank are recorded  Does the data bank contain pre-processed tables (i.e., curated by an organisation other	List of languages linked to ISO 639 codes (https://www.iso.org/iso-639-language-codes.html)  No/yes	Manual entry  Manual entry	С
F9C6.1.6 F9C6.1.7 F9C6.2 F9C6.3	C6.1.7	Data bank language	abridged version is entered  Languages in which that the records in the data bank are recorded  Does the data bank contain pre-processed	codes (https://www.iso.org/iso-639- language-codes.html)	Manual entry  Manual entry  Manual entry, in future implementations of the catalogue,	C C
F9C6.1.6 F9C6.1.7 F9C6.2 F9C6.3	C6.1.7 C6.2 C6.3	Data bank language  Processed tables  Processed tables description	abridged version is entered  Languages in which that the records in the data bank are recorded  Does the data bank contain pre-processed tables (i.e., curated by an organisation other than the DAP)?  If yes to the above, a description of the tables that are pre-processed  Is there a unique identifier for a person in the	codes (https://www.iso.org/iso-639-language-codes.html)  No/yes  Free text	Manual entry  Manual entry  Manual entry; in future	C C
F9C6.1.6 F9C6.1.7 F9C6.2 F9C6.3 F9C6.3.1	C6.1.7 C6.2 C6.3	Data bank language  Processed tables  Processed tables description	abridged version is entered  Languages in which that the records in the data bank are recorded  Does the data bank contain pre-processed tables (i.e., curated by an organisation other than the DAP)?  If yes to the above, a description of the tables that are pre-processed  Is there a unique identifier for a person in the	codes (https://www.iso.org/iso-639-language-codes.html)  No/yes  Free text  No/yes	Manual entry  Manual entry  Manual entry; in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry; in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language	C C C
F9C6.1.6 F9C6.1.7 F9C6.2 F9C6.3 F9C6.3.1	C6.1.7 C6.2 C6.3 C6.3.1	Data bank language  Processed tables  Processed tables description  Unique identifier  Unique identifier	abridged version is entered  Languages in which that the records in the data bank are recorded  Does the data bank contain pre-processed tables (i.e., curated by an organisation other than the DAP)?  If yes to the above, a description of the tables that are pre-processed  Is there a unique identifier for a person in the data bank?  Describe the variable that is used as a unique identifier for a person in the data bank? If the unique identifier is not at level of a person (for example hospital encounter), describe how this	codes (https://www.iso.org/iso-639-language-codes.html)  No/yes  Free text  No/yes	Manual entry  Manual entry; in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry; in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry; in future implementations of the catalogue,	C
F9C6.1.6 F9C6.1.7 F9C6.3 F9C6.3.1 F9C6.4	C6.1.7 C6.2 C6.3 C6.4 C6.4.1	Processed tables Processed tables description Unique identifier Unique identifier	abridged version is entered  Languages in which that the records in the data bank are recorded  Does the data bank contain pre-processed tables (i.e., curated by an organisation other than the DAP)?  If yes to the above, a description of the tables that are pre-processed  Is there a unique identifier for a person in the data bank?  Describe the variable that is used as a unique identifier for a person in the data bank? If the unique identifier is not at level of a person (for example hospital encounter), describe how this translated to an individual level.  Are data on geographic region available?	codes (https://www.iso.org/iso-639-language-codes.html)  No/yes  Free text  No/yes	Manual entry  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions	C C
F9C6.1.6 F9C6.1.7 F9C6.3 F9C6.3.1 F9C6.4	C6.1.7 C6.2 C6.3 C6.3.1 C6.4	Processed tables Processed tables description Unique identifier Unique identifier	abridged version is entered  Languages in which that the records in the data bank are recorded  Does the data bank contain pre-processed tables (i.e., curated by an organisation other than the DAP)?  If yes to the above, a description of the tables that are pre-processed  Is there a unique identifier for a person in the data bank?  Describe the variable that is used as a unique identifier for a person in the data bank? If the unique identifier is not at level of a person (for example hospital encounter), describe how this translated to an individual level.  Are data on geographic region available?  Can geographical can be identify?	codes (https://www.iso.org/iso-639-language-codes.html)  No/yes  Free text  No/yes	Manual entry  Manual entry; in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry; in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry; in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry; in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language this information could be extracted automatically from the data dictionary, if an English-language	C C C
F9C6.1.6 F9C6.2 F9C6.3 F9C6.4 F9C6.4	C6.1.7 C6.2 C6.3 C6.4 C6.4.1	Processed tables Processed tables description Unique identifier Unique identifier description Geographic regions	abridged version is entered  Languages in which that the records in the data bank are recorded  Does the data bank contain pre-processed tables (i.e., curated by an organisation other than the DAP)?  If yes to the above, a description of the tables that are pre-processed  Is there a unique identifier for a person in the data bank?  Describe the variable that is used as a unique identifier for a person in the data bank? If the unique identifier is not at level of a person (for example hospital encounter), describe how this translated to an individual level.  Are data on geographic region available?  Can geographical can be identify?	codes (https://www.iso.org/iso-639-language-codes.html)  No/yes  Free text  No/yes  No/yes  Household/ mother-child/ father-	Manual entry  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions	C C C
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F9C6.1.6 F9C6.2 F9C6.3 F9C6.4 F9C6.4 F9C6.6	C6.1.7 C6.2 C6.3 C6.3.1 C6.4 C6.4.1 C6.6	Processed tables Processed tables description Unique identifier description  Geographic regions  Familylinkage	abridged version is entered  Languages in which that the records in the data bank are recorded  Does the data bank contain pre-processed tables (i.e., curated by an organisation other than the DAP)?  If yes to the above, a description of the tables that are pre-processed Is there a unique identifier for a person in the data bank?  Describe the variable that is used as a unique identifier for a person in the data bank? If the unique identifier is not at level of a person (for example hospital encounter), describe how this translated to an individual level.  Are data on geographic region available?  Can geographical can be identify?  Is any linkage available in the data bank between any of the following persons?	codes (https://www.iso.org/iso-639-language-codes.html)  No/yes  Free text  No/yes  No/yes  Household/ mother-child/ father-child/ sibling	Manual entry  Manual entry; in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions	C C C C C C C C C C C C C C C C C C C
F9C6.1.6 F9C6.2 F9C6.3 F9C6.4 F9C6.4 F9C6.6	C6.1.7 C6.2 C6.3 C6.3.1 C6.4 C6.4.1 C6.6 C6.6	Data bank language  Processed tables  Processed tables description  Unique identifier description  Geographic regions  Family linkage  Family linkage routine	abridged version is entered  Languages in which that the records in the data bank are recorded  Does the data bank contain pre-processed tables (i.e., curated by an organisation other than the DAP)?  If yes to the above, a description of the tables that are pre-processed  Is there a unique identifier for a person in the data bank?  Describe the variable that is used as a unique identifier for a person in the data bank? If the unique identifier is not at level of a person (for example hospital encounter), describe how this translated to an individual level.  Are data on geographic region available?  Can geographical can be identify?  Is anylinkage available in the data bank between any of the following persons?  Is familial linkage created routinely or can linkage be performed on an ad-hoc basis?  Is familial linkage available for all of the data bank population or a subset of individuals (or records)?	codes (https://www.iso.org/iso-639-language-codes.html)  No/yes  Free text  No/yes  No/yes  Household/ mother-child/ father-child/ sibling  Routine/ad hoc	Manual entry  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions	C C C C C C C C C C C C C C C C C C C
F9C6.1.6 F9C6.2 F9C6.3 F9C6.4 F9C6.4 F9C6.4.1	C6.1.7 C6.2 C6.3 C6.4 C6.4 C6.6 C6.6 C6.6.1	Data bank language  Processed tables  Processed tables description  Unique identifier description  Geographic regions  Family linkage  Family linkage routine  Family linkage availability	abridged version is entered  Languages in which that the records in the data bank are recorded  Does the data bank contain pre-processed tables (i.e., curated by an organisation other than the DAP)?  If yes to the above, a description of the tables that are pre-processed  Is there a unique identifier for a person in the data bank?  Describe the variable that is used as a unique identifier for a person in the data bank? If the unique identifier is not at level of a person (for example hospital encounter), describe how this translated to an individual level.  Are data on geographic region available?  Can geographical can be identify?  Is any linkage available in the data bank between any of the following persons?  Is familial linkage created routinely or can linkage be performed on an ad-hoc basis?  Is familial linkage available for all of the data bank population or a subset of individuals (or records)?	codes (https://www.iso.org/iso-639-language-codes.html)  No/yes  Free text  No/yes  No/yes  Household/ mother-child/ father-child/ sibling  Routine/ad hoc	Manual entry  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions	C C C C C C C C C C C C C C C C C C C
F9C6.1.6 F9C6.2 F9C6.3 F9C6.4 F9C6.4 F9C6.6 F9C6.6	C6.1.7 C6.2 C6.3 C6.4 C6.4 C6.6 C6.6 C6.6.1	Data bank language  Processed tables  Processed tables description  Unique identifier description  Geographic regions  Family linkage  Family linkage routine  Family linkage availability	abridged version is entered  Languages in which that the records in the data bank are recorded  Does the data bank contain pre-processed tables (i.e., curated by an organisation other than the DAP)?  If yes to the above, a description of the tables that are pre-processed  Is there a unique identifier for a person in the data bank?  Describe the variable that is used as a unique identifier for a person in the data bank? If the unique identifier is not at level of a person (for example hospital encounter), describe how this translated to an individual level.  Are data on geographic region available?  Can geographical can be identify?  Is anylinkage available in the data bank between any of the following persons?  Is familial linkage created routinely or can linkage be performed on an ad-hoc basis?  Is familial linkage available for all of the data bank population or a subset of individuals (or records)?	codes (https://www.iso.org/iso-639-language-codes.html)  No/yes  Free text  No/yes  Free text  No/yes  Household/ mother-child/ father-child/ sibling  Routine/ad hoc  Full/subset  Free text  None/ age/ sex/ gender/ ethnicity/ country of origin/ socioeconomic status/ marital status/ education level/ type of residency/ living in rural are/a/ health area/ deprivation index/	Manual entry  Manual entry  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions	C C C C C C C C C C C C C C C C C C C
F9C6.1.6 F9C6.2 F9C6.4 F9C6.4 F9C6.6 F9C6.6 F9C6.6.7	C6.1.7 C6.2 C6.3 C6.4 C6.4 C6.6.1 C6.6.1	Data bank language  Processed tables  Processed tables description  Unique identifier  Geographic regions  Family linkage  Family linkage availability details  Sociodemographics included	abridged version is entered  Languages in which that the records in the data bank are recorded  Does the data bank contain pre-processed tables (i.e., curated by an organisation other than the DAP)?  If yes to the above, a description of the tables that are pre-processed  Is there a unique identifier for a person in the data bank?  Describe the variable that is used as a unique identifier for a person in the data bank? If the unique identifier is not at level of a person (for example hospital encounter), describe how this translated to an individual level.  Are data on geographic region available?  Can geographical can be identify?  Is anyllinkage available in the data bank between any of the following persons?  Is familial linkage created routinely or can linkage be performed on an ad-hoc basis?  Is familial linkage available for all of the data bank population or a subset of individuals (or records)?  If a familial linkage is available for a subset of individuals (or records)?  Which of the following sociodemographic information is included? Select all that apply.  Which of the following lifestyle information is	codes (https://www.iso.org/iso-639-language-codes.html)  No/yes  Free text  No/yes  Free text  No/yes  Household/ mother-child/ father-child/ sibling  Routine/ad hoc  Full/subset  Free text  None/ age/ sex/ gender/ ethnicity/ country of origin/ socioeconomic status/ type of residency living in rural area/ health area/ deprivation index/ pharmaceutical copayment/ other  None/ tobacco use/ alcohol use/	Manual entry  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions	C C C C C C C C C C C C C C C C C C C
F9C6.1.6 F9C6.2 F9C6.4 F9C6.4 F9C6.6 F9C6.6 F9C6.6.7	C6.1.7 C6.2 C6.3 C6.4 C6.4 C6.5 C6.6 C6.6.1	Data bank language  Processed tables description  Unique identifier  Geographic regions  Family linkage  Family linkage availability details  Sociodemographics included	abridged version is entered  Languages in which that the records in the data bank are recorded  Does the data bank contain pre-processed tables (i.e., curated by an organisation other than the DAP)?  If yes to the above, a description of the tables that are pre-processed  Is there a unique identifier for a person in the data bank?  Describe the variable that is used as a unique identifier for a person in the data bank? If the unique identifier is not at level of a person for example hospital encounter), describe how this translated to an individual level.  Are data on geographic region available?  Can geographical can be identify?  Is anylinkage available in the data bank between any of the following persons?  Is familial linkage created routinely or can linkage be performed on an ad-hoc basis?  Is familial linkage available for all of the data bank population or a subset of individuals (or records)?  If a familial linkage is available for all of the data bank population or a subset of individuals (or records)?	codes (https://www.iso.org/iso-639-language-codes.html)  No/yes  Free text  No/yes  Free text  No/yes  Household/ mother-child/ father-child/ sibling  Routine/ad hoc  Full/subset  Free text  None/ age/ sex/ gender/ ethnicity/ country of origin/ socioeconomic status/ type of residency living in rural area/ health area/ deprivation index/ pharmaceutical copayment/ other	Manual entry  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information from the data dictionary, if an English-language version is uploaded, using scripts of functions	C C C C C C C C C C C C C C C C C C C
F9C6.1.6 F9C6.2 F9C6.3 F9C6.4 F9C6.4 F9C6.6 F9C6.6.7 F9C6.6.3	C6.1.7 C6.2 C6.3 C6.4 C6.4 C6.5 C6.6 C6.6.1	Data bank language  Processed tables  Processed tables description  Unique identifier  Geographic regions  Family linkage  Family linkage availability details  Sociodemographics included	abridged version is entered  Languages in which that the records in the data bank are recorded  Does the data bank contain pre-processed tables (i.e., curated by an organisation other than the DAP)?  If yes to the above, a description of the tables that are pre-processed  Is there a unique identifier for a person in the data bank?  Describe the variable that is used as a unique identifier for a person in the data bank? If the unique identifier is not at level of a person (for example hospital encounter), describe how this translated to an individual level.  Are data on geographic region available?  Can geographical can be identify?  Is anyllinkage available in the data bank between any of the following persons?  Is familial linkage created routinely or can linkage be performed on an ad-hoc basis?  Is familial linkage available for all of the data bank population or a subset of individuals (or records)?  If a familial linkage is available for a subset of individuals (or records)?  Which of the following sociodemographic information is included? Select all that apply.  Which of the following lifestyle information is	codes (https://www.iso.org/iso-639-language-codes.html)  No/yes  Free text  No/yes  Free text  No/yes  Household/ mother-child/ father-child/ sibling  Routine/ad hoc  Full/subset  Free text  None/ age/ sex/ gender/ ethnicity/ country of origin/ socioeconomic status/ type of residency living in rural area/ health area/ deprivation index/ pharmaceutical copayment/ other  None/ tobacco use/ alcohol use/	Manual entry  Manual entry; in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions	C C C C C C C C C C C C C C C C C C C



			following:	ICPC/ ICD9/ ICD10/ ICD1/ Read/ SNOMED/ SNOMED CT/ MedDRA/ OPCS/ CCS/ EDC/ Not coded (Free text)/ Other	Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions	
F9C6.9.1		Diagnosis, other	percentage of records are not coded?  Is other information on diagnoses of patient outcomes recorded, not in the form of	Unit: %, not applicable Free text	Manual entry C  Manual entry, in future C implementations of the catalogue,	
F9C6.9.3		Hospital admission	•	No/yes	this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future  C	
F9C6.10			hospital discharge available?  Is information on intensive care unit admission	No/yes	implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future  C	
F9C6.10.1	G0.10.1		available?	ivo, yes	implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions	
	C6.11	Cause of death	Is cause of death available?	No/yes	Manual entry, in future  implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions	
F9C6.11	C6.11.1	_	Ç	ICPC/ ICD9/ ICD10/ ICD1/ Read/ SNOMED/ SNOMED CT/ MedDRA/ OPCS/ CCS/ EDC/ Not coded (Free text)/ Other	Manual entry, in future  implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of	
F9C6.11.2			percentage of records are not coded?	Unit: %, not applicable Free text	functions  Manual entry  C  Manual entry; in future  C	
F9C6.11.3	C6.12	Rare diseases	Are rare diseases (<1 in 2000 people)	No/yes	implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future  C	
F9C6.12	C6.12		captured?	ivo/yes	implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions	
			Is information on prescription of medications included?	No/yes	Manual entry, in future  implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions	
F9C6.13	C6.13.1		_	ATC/ RxNorm/ EphMRA/ ALT/ Drug Bank/ Not coded (Free text)/ Other	Manual entry, in future  implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of	
F9C6.13.2	C6.13.3		percentage of records are not coded?	Unit: %, not applicable Free text	functions  Manual entry  C  Manual entry, in future implementations of the catalogue,	
F9C6.13.3			Is information on dispensing of medications	No/yes	this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future  C	
F9C6.14			included?		implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions	
	C6.14.1	, ,	_	ATC/ RxNorm/ EphMRA/ ALT/ Drug Bank/ Not coded (Free text)/ Other	Manual entry, in future C implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions	
F9C6.14.2	C6.14.3		percentage of records are not coded?	Unit: %, not applicable Free text	Manual entry C  Manual entry, in future cimplementations of the catalogue, this information could be extracted	
F9C6.14.3	C6.15		items that apply.	Brand name/ batch number/ formulation/ strength/ package size	automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue,	
F9C6.15		Product information,	If product information is included, what	Dose/ dosage regime/ route of administration/ product information  ART 57/ IFA GmbH/ EQDM/ SPN/	this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future  C	
F9C6.15.1				MTHSPL/ Not coded (Free text)/ Other	implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions	
F9C6.15.2	C6.15.2	Product vocabulary, other	If 'other,' what vocabulary is used?	Free text	Manual entry, in future  implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions	
F900.13.2		· ·	vocabulary is used to describe the substance?	ART 57/ IFA GmbH/ EQDM/ SPN/ MTHSPL/ Not coded (Free text)/ Other	Manual entry, in future  implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of	
F9C6.15.3	C6.15.4	Substance vocabulary, other	,	Free text ATC/ RxNorm/ EphMRA/ ALT/ DrugBank/ Not coded (Free text)/ Other	functions  Manual entry, in future  implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of	
F9C6.15.4	C6.15.5		Is other information on medicines or products included?	No/yes	functions  Manual entry, in future  implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language	
F9C6.15.5	C6.15.6			Dose/ dosage regime/ route of administration/ product information	version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data	
F9C6.15.6	C6.16		Is information on advanced therapy medicinal products included?	No/yes	dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data	
F9C6.16	C6.17	Contraception	Is information on contraceptives included?	No/yes	dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future cimplementations of the catalogue, this information could be extracted	
F9C6.17	C6.17.1		If yes, is information on emergency contraceptives included?	No/yes	automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue,	
F9C6.17.1	C6.18		•	No/yes/not applicable	this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future  C	
F9C6.18	C6.18.1		indication for use recorded?  If yes, what vocabulary is used? Select from the	ICPC/ ICD9/ ICD10/ ICD1/ Read/	implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future  C	
F9C6.18. <sup>4</sup>	G 6. 16. 1	•	following:	SNOMED/ SNOMED CT/	implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions	
F9C6.18.2			percentage of records are not coded?	Unit: %, not applicable  Free text	Manual entry  Manual entry, in future  implementations of the catalogue, this information could be extracted automatically from the data	
F9C6.18.3			Is information on the administration of vaccines included?	No/yes	dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted	
F9C6.19	C6.19.1		Is information on the administration of other injectable medicines included?	No/yes	automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted	
F9C6.19. <sup>2</sup>	C6.20	Medical devices	Is information on medical devices included?	No/yes	automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue,	
F9C6.20	C6.21			No/yes	this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future  C	
F9C6.21	C6.22.1	Procedures not coded	, , , , , ,	Unit: %, not applicable	implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry  C	
F9C6.22.		Procedures vocabulary	percentage of records are not coded?  If yes, what vocabulary is used? Select from the following:	ICPC/ ICD9/ ICD10/ ICD1/ Read/ SNOMED/ SNOMED CT/ MedDRA/ OPCS/ CCS/ EDC/ Not coded (Free text)/ Other	Manual entry, in future  implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language	
F9C6.22		Procedure vocabulary, other	If 'other,' what vocabulary is used?	Free text	version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted automatically from the data	
F9C6.22.2	C6.22.3	Procedure results	Are results of procedures available?	No/yes	dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted	
F9C6.22.3			following:	ICPC/ ICD9/ ICD10/ ICD1/ Read/ SNOMED/ SNOMED CT/ MedDRA/ OPCS/ CCS/ EDC/ Not	automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted	
F9C6.22.4				Unit: %, not applicable	automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry  C	
F9C6.22.5	C6.22.6		-	Free text	Manual entry, in future  implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of	
F9C6.22.6			Is information on clinical measures included (e.g., BMI, blood pressure)?	No/yes	functions  Manual entry, in future  implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language	
F9C6.23	C6.24		Is information on the healthcare centre (e.g., pharmacy, general practice, hospital) available?	No/yes	version is uploaded, using scripts of functions  Manual entry, in future  implementations of the catalogue, this information could be extracted automatically from the data	
F9C6.24	C6.24.1		Is information on the person providing healthcare (e.g., physician, pharmacist, specialist) available?	No/yes	dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted	
F9C6.24.	C6.25	Genetic data	Is genotyping information available?	No/yes	automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry, in future implementations of the catalogue, this information could be extracted	
F9C6.25	C6.25.1	Genetic data v ocabulary	If yes, what vocabulary is used? Select from the following:	OGG/ FG/ GO/ EGO/ SOPHARM/ PHARE/ other	automatically from the data dictionary, if an English-language version is uploaded, using scripts of functions  Manual entry; in future implementations of the	
		जाजा y	and ronowing:	I LIANE/ Other	implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an Englishlanguage version is uploaded, using scripts of	
F9C6.25.1	C6.25.2	Genetic data v ocabulary , other	If 'other,' what vocabulary is used?	Free text	functions  Manual entry; in future  implementations of the catalogue, this information could be extracted automatically from the data	
F9C6.25.2	C6.25.3	Genetic data summary	A short summary of how genetic information is captured in the data	Free text	dictionary, if an English- language version is uploaded, using scripts of functions  Manual entry; in future implementations of the	
			source.		catalogue, this information could be extracted automatically from the data dictionary, if an English- language version is uploaded, using scripts of	
F9C6.25.3			i	<u>I</u>	functions	

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	C6.26	Biomarker data	Is biomarker information available?	No/y es	Manual entry; in future	C
					implementations of the catalogue, this information could be extracted	
					automatically from the data dictionary, if an English- language version is	
F9C6.26	C6.26.1	Biomarker data	If yes, what vocabulary is used?	BMO/ SMASH/ FOBI/ other	uploaded, using scripts of functions	С
	C0.20. 1	v ocabulary	Select from the following:	DIVIO/ SIVIASH/ FOBI/ OTHER	implementations of the catalogue, this information	C
					could be extracted automatically from the data dictionary, if an English-	
F9C6.26.					language version is uploaded, using scripts of functions	
	C6.26.2	Biomarker data v ocabulary , other	If 'other,' what vocabulary is used?	Free text	Manual entry; in future implementations of the catalogue, this information	С
					could be extracted automatically from the data	
					dictionary, if an English- language version is uploaded, using scripts of	
F9C6.26.2	C6.26.3	Biomarker data	A short summary of how biomarker	Free text	functions  Manual entry; in future	С
		summary	information is captured in the data source.		implementations of the catalogue, this information could be extracted	
					automatically from the data dictionary, if an English- language version is	
F9C6.26.3					uploaded, using scripts of functions	
	C6.27	Patient-generated data	Is patient-generated information (e.g., from wearable devices) available?		Manual entry, in future implementations of the catalogue, this information could be extracted	С
					automatically from the data dictionary, if an English-language version is uploaded, using scripts of	
F9C6.27	C6.27.1	Patient-generated data summary	A short summary of how patient-generated information (e.g., from wearable devices) is	Free text	functions  Manual entry, in future implementations of the catalogue,	С
		Samma y	captured in the data bank.		this information could be extracted automatically from the data dictionary, if an English-language	
F9C6.27.					version is uploaded, using scripts of functions	
	C6.28	Quality of life included	Are quality of life measures available? Select all that apply.		implementations of the catalogue, this information could be extracted	С
					automatically from the data dictionary, if an English-language version is uploaded, using scripts of	
F9C6.28	C6.28.1	Quality of life, other	If 'other,' specify additional quality of life	Free text	3,	С
			measures.		implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language	
F9C6.28.					dictionary, if an English-language version is uploaded, using scripts of functions	
JUU.28.	C6.29	Costs	Is information on costs of healthcare available?		Manual entry, in future implementations of the catalogue, this information could be extracted	С
					this information could be extracted automatically from the data dictionary, if an English-language version is uploaded, using scripts of	
F9C6.29	C6.30	Free text	Is free text information available?	No/yes	version is uploaded, using scripts of functions  Manual entry, in future	С
					implementations of the catalogue, this information could be extracted automatically from the data	
					dictionary, if an English-language version is uploaded, using scripts of functions	
F9C6.30	C6.30.1	Use of NLP	Is natural language processing used to process free text information into standardised	No/yes/not applicable	Manual entry, in future implementations of the catalogue,	С
			information?		this information could be extracted automatically from the data dictionary, if an English-language	
F9C6.30.	0000	Davin Str.	If not well		version is uploaded, using scripts of functions	
	C6.30.2	Details of NLP	If natural language processing is used, provide a summary description of how natural language processing is used.		implementations of the catalogue, this information could be extracted	С
					automatically from the data dictionary, if an English-language version is uploaded, using scripts of	
F9C6.30.2	C6.30.3	Deidentified text	Are procedures in place to de-identify or remove personal information from free text?	No/yes/not applicable	functions  Manual entry, in future implementations of the catalogue	С
			remove personal information from free text?		implementations of the catalogue, this information could be extracted automatically from the data dictionary, if an English-language	
F9C6.30.3					dictionary, if an English-language version is uploaded, using scripts of functions	
1 900.30.	C7.1	Population size	Total number of unique individuals with records captured in the data bank (most recent count). In the catalogue, this will accommodate counts		Manual entry, in future implementations scripts or functions could work tog ether with a common	С
			per year.		data model to extract this information directly from a data bank	
F9C7.1	C7.1.1	Population size active	Number of unique, active, or currently registered individuals with records captured in	Numeric	Manual entry, in future implementations scripts or functions	С
			the data source (most recent count). In the catalogue, this will accommodate counts per year.		could work tog ether with a common data model to extract this information directly from a data bank	
F9C7.1.1	C7.2	Number of individuals	•	Numeric	Manual entry, in future	С
		with biological samples	biological samples (e.g., blood, urine) (most recent count). In the catalogue, this will accommodate counts per year.		implementations scripts or functions could work together with a common data model to extract this information	
F9C7.2	C7.3	Population size by age	Total number of unique individuals with records	Numeric, for each of the following	directly from a data bank  Manual entry, in future	С
			captured in the data bank (most recent count), stratified by age. The time point at which age will be calculated will need to be specified	categories: newborn infants (0 to 27 days), infants and toddlers (28 days to 23 months), children (2 to 11	implementations scripts or functions could work together with a common data model to extract this information	
				years), adolescents (12 to 17 years), adults (18 to 45 years), adults (46 to 64 years), adults (65 to 75 years),	directly from a data bank	
				adults (76 years and over)		
F9C7.3	C7.3.1	Population size active by age	•	Numeric, for each of the following categories: newborn infants (0 to 27	Manual entry, in future implementations scripts or functions	С
			the data bank (most recent count), stratified by age	years), adolescents (12 to 17 years),	could work tog ether with a common data model to extract this information directly from a data bank	
				adults (18 to 45 years), adults (46 to 64 years), adults (65 to 75 years), adults (76 years and over)		
F9C7.3.1						
	C7.4	Median age data bank	Median age of individuals within the data bank	Numeric	implementations scripts or functions could work together with a common	С
					data model to extract this information directly from a data bank	
F9C7.4			Proportion of females in the data bank	Unit: %	implementations scripts or functions	С
F9C7.4	C7.5	Proportion female data bank			could work together with a common	
	C7.5	·			could work tog ether with a common data model to extract this information directly from a data bank	
	C7.5	·	Proportion of people per ethnicity in the data bank	Unit: %, per ethnicity group	data model to extract this information directly from a data bank  Manual entry, in future implementations scripts or functions	С
F9C7.5		bank Proportion ethnicity		Unit: %, per ethnicity group	data model to extract this information directly from a data bank  Manual entry, in future	
F9C7.5		bank Proportion ethnicity	bank		data model to extract this information directly from a data bank  Manual entry, in future implementations scripts or functions could work tog ether with a common data model to extract this information directly from a data bank	
F9C7.5	C7.6	Proportion ethnicity data bank	Average number of days between refresh of data bank with new records	Unit: days	data model to extract this information directly from a data bank  Manual entry, in future implementations scripts or functions could work tog ether with a common data model to extract this information directly from a data bank  Manual entry	
F9C7.5 F9C7.6 F9C8.1	C7.6  C8.1  C8.2	Proportion ethnicity data bank  Data bank refresh  Data bank refresh period	Average number of days between refresh of data bank with new records  If data are refreshed on fixed dates (e.g., every June and December), when are the refreshes scheduled? Select all that apply from the following:  Date of last update/refresh	Unit: days  January/ February/ March/ April/ May/ June/ July/ August/ September/ October/ November/ December  DDMMYYY	data model to extract this information directly from a data bank  Manual entry, in future implementations scripts or functions could work together with a common data model to extract this information directly from a data bank  Manual entry  Manual entry	C
F9C7.5 F9C7.6 F9C8.1 F9C8.2 F9C8.3	C7.6 C8.1 C8.2	Proportion ethnicity data bank  Data bank refresh  Data bank refresh period	Average number of days between refresh of data bank with new records  If data are refreshed on fixed dates (e.g., every June and December), when are the refreshes scheduled? Select all that apply from the following:  Date of last update/refresh	Unit: days  January/ February/ March/ April/ May/ June/ July/ August/ September/ October/ November/ December  DDMMYYY  Unit: days	data model to extract this information directly from a data bank  Manual entry, in future implementations scripts or functions could work together with a common data model to extract this information directly from a data bank  Manual entry  Manual entry	C
F9C7.5 F9C7.6 F9C8.1 F9C8.2 F9C8.3	C7.6  C8.1  C8.2  C8.3  C8.4	Proportion ethnicity data bank  Data bank refresh  Data bank refresh period  Data bank last refresh  Data bank last refresh  Data bank lag	Average number of days between refresh of data bank with new records  If data are refreshed on fixed dates (e.g., every June and December), when are the refreshes scheduled? Select all that apply from the following:  Date of last update/refresh  How long is the lag time after refresh before a record can be extracted? (e.g., a lag time may occur if the originator conducts quality checks)  Are records preserved in the data bank indefinitely?	Unit: days  January/ February/ March/ April/ May/ June/ July/ August/ September/ October/ November/ December  DDMMYYY  Unit: days	data model to extract this information directly from a data bank  Manual entry, in future implementations scripts or functions could work tog ether with a common data model to extract this information directly from a data bank  Manual entry  Manual entry  Manual entry  Manual entry  Manual entry	C C C
F9C7.5 F9C7.6 F9C8.1 F9C8.2 F9C8.3 F9C8.5	C7.6  C8.1  C8.2  C8.3  C8.4  C8.5	Proportion ethnicity data bank  Data bank refresh  Data bank refresh period  Data bank last refresh  Data bank last	Average number of days between refresh of data bank with new records  If data are refreshed on fixed dates (e.g., every June and December), when are the refreshes scheduled? Select all that apply from the following:  Date of last update/refresh  How long is the lag time after refresh before a record can be extracted? (e.g., a lag time may occur if the originator conducts quality checks)  Are records preserved in the data bank indefinitely?  If no to the above, for how long are records preserved in the data bank?  Provide a description of any major changes to	Unit: days  January/ February/ March/ April/ May/ June/ July/ August/ September/ October/ November/ December  DDMMYYY  Unit: days  No/yes  Unit: years	data model to extract this information directly from a data bank  Manual entry, in future implementations scripts or functions could work tog ether with a common data model to extract this information directly from a data bank  Manual entry  Manual entry  Manual entry  Manual entry  Manual entry  Manual entry	C C
F9C7.5 F9C7.6 F9C8.1 F9C8.2 F9C8.3 F9C8.5	C7.6  C8.1  C8.2  C8.3  C8.4  C8.5  C8.5	Proportion ethnicity data bank  Data bank refresh  Data bank refresh period  Data bank last refresh  Data bank last refresh  Data bank lag  Data bank preservation  Data bank preservation length	Average number of days between refresh of data bank with new records  If data are refreshed on fixed dates (e.g., every June and December), when are the refreshes scheduled? Select all that apply from the following:  Date of last update/refresh  How long is the lag time after refresh before a record can be extracted? (e.g., a lag time may occur if the originator conducts quality checks)  Are records preserved in the data bank indefinitely?  If no to the above, for how long are records preserved in the data bank?	Unit: days  January/ February/ March/ April/ May/ June/ July/ August/ September/ October/ November/ December  DDMMYYY Unit: days  No/yes  Unit: years  Free text	data model to extract this information directly from a data bank  Manual entry, in future implementations scripts or functions could work tog ether with a common data model to extract this information directly from a data bank  Manual entry  Manual entry  Manual entry  Manual entry  Manual entry  Manual entry	C C C
F9C7.5 F9C7.6 F9C8.1 F9C8.2 F9C8.3 F9C8.5 F9C8.5	C7.6  C8.1  C8.2  C8.3  C8.4  C8.5  C8.5	Proportion ethnicity data bank  Data bank refresh  Data bank refresh period  Data bank last refresh  Data bank last refresh  Data bank lag  Data bank preservation  Data bank preservation length	Average number of days between refresh of data bank with new records  If data are refreshed on fixed dates (e.g., every June and December), when are the refreshes scheduled? Select all that apply from the following:  Date of last update/refresh  How long is the lag time after refresh before a record can be extracted? (e.g., a lag time may occur if the originator conducts quality checks)  Are records preserved in the data bank indefinitely?  If no to the above, for how long are records preserved in the data bank?  Provide a description of any major changes to the data bank that have occurred over time, including updates in its data model, prompts, or	Unit: days  January/ February/ March/ April/ May/ June/ July/ August/ September/ October/ November/ December  DDMMYYY Unit: days  No/yes  Unit: years  Free text	data model to extract this information directly from a data bank  Manual entry, in future implementations scripts or functions could work tog ether with a common data model to extract this information directly from a data bank  Manual entry	C C C
F9C7.5 F9C7.6 F9C8.1 F9C8.2 F9C8.3 F9C8.5 F9C8.5	C8.1 C8.2 C8.3 C8.4 C8.5 C8.5.1 C8.6	Proportion ethnicity data bank  Data bank refresh  Data bank refresh period  Data bank last refresh  Data bank lasg  Data bank preservation  Data bank preservation length  Data bank changes	Average number of days between refresh of data bank with new records  If data are refreshed on fixed dates (e.g., every June and December), when are the refreshes scheduled? Select all that apply from the following:  Date of last update/refresh  How long is the lag time after refresh before a record can be extracted? (e.g., a lag time may occur if the originator conducts quality checks)  Are records preserved in the data bank indefinitely?  If no to the above, for how long are records preserved in the data bank?  Provide a description of any major changes to the data bank that have occurred over time, including updates in its data model, prompts, or underlying population.  Total number of unique records captured in the data bank (most recent count)	Unit: days  January/ February/ March/ April/ May/ June/ July/ August/ September/ October/ November/ December  DDMMYYY Unit: days  No/yes  Unit: years  Free text	data model to extract this information directly from a data bank  Manual entry, in future implementations scripts or functions could work tog ether with a common data model to extract this information directly from a data bank  Manual entry	C C C C C
F9C7.5 F9C7.6 F9C8.1 F9C8.2 F9C8.3 F9C8.5 F9C8.5 F9C8.5.1	C7.6  C8.1  C8.2  C8.3  C8.4  C8.5  C8.5.1  C8.6	Proportion ethnicity data bank  Data bank refresh period  Data bank last refresh Data bank last refresh Data bank lag  Data bank preservation  Data bank preservation length Data bank changes  Number of records  Number of excluded records  Comment completeness	Average number of days between refresh of data bank with new records  If data are refreshed on fixed dates (e.g., every June and December), when are the refreshes scheduled? Select all that apply from the following:  Date of last update/refresh  How long is the lag time after refresh before a record can be extracted? (e.g., a lag time may occur if the originator conducts quality checks)  Are records preserved in the data bank indefinitely?  If no to the above, for how long are records preserved in the data bank?  Provide a description of any major changes to the data bank that have occurred over time, including updates in its data model, prompts, or underlying population.  Total number of unique records captured in the data bank (most recent count)  If records were excluded following quality checks or a quality assurance process, the total number of unique records that were excluded  Describe the completeness of the data bank	Unit: days  January/ February/ March/ April/ May/ June/ July/ August/ September/ October/ November/ December  DDMMYYY Unit: days  No/yes  Unit: years  Free text  Numeric  Numeric	data model to extract this information directly from a data bank  Manual entry, in future implementations scripts or functions could work together with a common data model to extract this information directly from a data bank  Manual entry	C C C C C C
F9C7.5 F9C7.6 F9C8.1 F9C8.2 F9C8.3 F9C8.5 F9C8.5 F9C8.5.1	C7.6  C8.1  C8.2  C8.3  C8.4  C8.5  C8.5.1  C8.6  C9.1	Proportion ethnicity data bank  Data bank refresh  Data bank refresh period  Data bank last refresh  Data bank lasg  Data bank preservation  Data bank preservation  length  Data bank changes  Number of excluded records  Comment completeness missing values  Comment completeness	Average number of days between refresh of data bank with new records  If data are refreshed on fixed dates (e.g., every June and December), when are the refreshes scheduled? Select all that apply from the following:  Date of last update/refresh  How long is the lag time after refresh before a record can be extracted? (e.g., a lag time may occur if the originator conducts quality checks)  Are records preserved in the data bank indefinitely?  If no to the above, for how long are records preserved in the data bank?  Provide a description of any major changes to the data bank that have occurred over time, including updates in its data model, prompts, or underlying population.  Total number of unique records captured in the data bank (most recent count)  If records were excluded following quality checks or a quality assurance process, the total number of unique records that were excluded  Describe the completeness of the data bank (e.g., variables with more or fewer missing values).  Describe any changes in completeness of the	Unit: days  January/ February/ March/ April/ May/ June/ July/ August/ September/ October/ November/ December  DDMMYYY Unit: days  No/yes  Unit: years  Free text  Numeric  Numeric	data model to extract this information directly from a data bank  Manual entry; in future implementations scripts or functions could work tog ether with a common data model to extract this information directly from a data bank  Manual entry	C C C C C C C C C C C C C C C C C C C
F9C7.5 F9C7.6 F9C8.1 F9C8.2 F9C8.3 F9C8.5 F9C8.5.1 F9C8.6 F9C9.1 F9C9.2 F9C9.3	C7.6  C8.1  C8.2  C8.3  C8.4  C8.5  C8.5.1  C8.6  C9.1  C9.2	Proportion ethnicity data bank  Data bank refresh Data bank refresh period  Data bank last refresh Data bank lag  Data bank preservation  Data bank preservation length  Data bank changes  Number of excluded records  Comment completeness missing values  Comment completeness missing values over time	Average number of days between refresh of data bank with new records  If data are refreshed on fixed dates (e.g., every June and December), when are the refreshes scheduled? Select all that apply from the following:  Date of last update/refresh  How long is the lag time after refresh before a record can be extracted? (e.g., a lag time may occur if the originator conducts quality checks)  Are records preserved in the data bank indefinitely?  If no to the above, for how long are records preserved in the data bank?  Provide a description of any major changes to the data bank that have occurred over time, including updates in its data model, prompts, or underlying population.  Total number of unique records captured in the data bank (most recent count)  If records were excluded following quality checks or a quality assurance process, the total number of unique records that were excluded  Describe the completeness of the data bank (e.g., variables with more or fewer missing values).  Describe any changes in completeness of the data bank (e.g., variables with more or fewer missing values) that have occurred over time.	Unit: days  January/ February/ March/ April/ May/ June/ July/ August/ September/ October/ November/ December  DDMMYYY Unit: days  No/yes  Unit: years  Free text  Numeric  Numeric  Free text	data model to extract this information directly from a data bank  Manual entry, in future implementations scripts or functions could work together with a common data model to extract this information directly from a data bank  Manual entry	C C C C C C C C C C C C C C C C C C C
F9C7.4 F9C7.5 F9C7.6 F9C8.1 F9C8.2 F9C8.3 F9C8.5 F9C8.5.1 F9C8.5 F9C8.5.1	C7.6  C8.1  C8.2  C8.3  C8.4  C8.5  C8.5.1  C8.6  C9.1  C9.2	Proportion ethnicity data bank  Data bank refresh Data bank refresh period  Data bank last refresh Data bank lag  Data bank preservation  Data bank preservation length  Data bank changes  Number of excluded records  Comment completeness missing values  Comment completeness missing values over time	Average number of days between refresh of data bank with new records  If data are refreshed on fixed dates (e.g., every June and December), when are the refreshes scheduled? Select all that apply from the following:  Date of last update/refresh  How long is the lag time after refresh before a record can be extracted? (e.g., a lag time may occur if the originator conducts quality checks)  Are records preserved in the data bank indefinitely?  If no to the above, for how long are records preserved in the data bank?  Provide a description of any major changes to the data bank that have occurred over time, including updates in its data model, prompts, or underlying population.  Total number of unique records captured in the data bank (most recent count)  If records were excluded following quality checks or a quality assurance process, the total number of unique records that were excluded  Describe the completeness of the data bank (e.g., variables with more or fewer missing values).  Describe any changes in completeness of the data bank (e.g., variables with more or fewer missing values) that have occurred over time.	Unit: days  January/ February/ March/ April/ May/ June/ July/ August/ September/ October/ November/ December  DDMMYYY Unit: days  No/yes Unit: years  Free text  Numeric  Numeric	data model to extract this information directly from a data bank  Manual entry, in future implementations scripts or functions could work together with a common data model to extract this information directly from a data bank  Manual entry	C C C C C C C C C C C C C C C C C C C
F9C7.5 F9C7.6 F9C8.1 F9C8.2 F9C8.3 F9C8.5 F9C8.5.1 F9C8.6 F9C9.1 F9C9.2 F9C9.3	C7.6  C8.1  C8.2  C8.3  C8.4  C8.5  C8.5  C8.6  C9.1  C9.2  C9.3	Proportion ethnicity data bank  Data bank refresh Data bank refresh period  Data bank last refresh Data bank last Data bank preservation  Data bank preservation length Data bank changes  Number of records  Number of excluded records  Comment completeness missing values  Comment completeness missing values over time  Comment completeness missing values subpopulations	Average number of days between refresh of data bank with new records  If data are refreshed on fixed dates (e.g., every June and December), when are the refreshes scheduled? Select all that apply from the following:  Date of last update/refresh  How long is the lag time after refresh before a record can be extracted? (e.g., a lag time may occur if the originator conducts quality checks)  Are records preserved in the data bank indefinitely?  If no to the above, for how long are records preserved in the data bank?  Provide a description of any major changes to the data bank that have occurred over time, including updates in its data model, prompts, or underlying population.  Total number of unique records captured in the data bank (most recent count)  If records were excluded following quality checks or a quality assurance process, the total number of unique records that were excluded  Describe the completeness of the data bank (e.g., variables with more or fewer missing values).  Describe any changes in completeness of the data bank (e.g., variables with more or fewer missing values) that have occurred over time.  Describe any differences in completeness of the data bank (e.g., variables with more or fewer missing values) that have occurred over time.	Unit: days  January/ February/ March/ April/ May/ June/ July/ August/ September/ October/ November/ December  DDMMYYY Unit: days  No/yes  Unit: years  Free text  Numeric  Free text  Free text  Free text	data model to extract this information directly from a data bank  Manual entry, in future implementations scripts or functions could work tog ether with a common data model to extract this information directly from a data bank  Manual entry	C C C C C C C C C C C C C C C C C C C
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F9C7.5  F9C7.6  F9C8.1  F9C8.2  F9C8.5  F9C8.5.1  F9C9.3.1  F9C9.3.1  F9C9.3.1  F9C9.3.2  F9C9.3.1  F9C9.3.2  F9C9.5.1  F9C9.5.1  F9C9.5.1  F9C9.5.1	C7.6  C8.1  C8.2  C8.3  C8.4  C8.5  C8.5  C8.6  C9.1  C9.2  C9.3  C9.3.1  C9.3.2  C9.4  C9.4.2  C9.5  C9.5  C9.5.3  C9.5.5  C9.5.6  C10.1	Proportion ethnicity data bank  Data bank refresh  Data bank refresh period  Data bank last refresh Data bank last refresh Data bank preservation length  Data bank changes  Number of records  Number of excluded records  Comment completeness missing values over time  Comment quality  Comment quality  Comment quality over time  Comment quality check and validation frequency  Data quality check and validation results  Data pank studies  Data bank studies	Average number of days between refresh of data bank with new records if data are refreshed on fixed dates (e.g., every June and December), when are the refreshes scheduled? Select all that apply from the following:  Date of last update/refresh  How long is the lag time after refresh before a record can be extracted? (e.g., a lag time may occur if the originator conducts quality checks)  Are records preserved in the data bank indefinitely?  If no to the above, for how long are records preserved in the data bank?  Prowde a description of any major changes to the data bank that have occurred over time, including updates in its data model, prompts, or underlying population.  Total number of unique records captured in the data bank (most recent count)  If records were excluded following quality checks or a quality assurance process, the total number of unique records that were excluded  Describe the completeness of the data bank (e.g., variables with more or fewer missing values).  Describe any changes in completeness of the data bank (e.g., variables with more or fewer missing values) that have occurred over time.  Describe any differences in completeness of the data bank (e.g., variables with more or fewer missing values) that have occurred over time.  Describe any changes in quality of the data bank (e.g., variables with more or fewer missing values) that have occurred over time.  Describe any differences in quality of the data bank (e.g., variables with more or fewer missing values) that have occurred over time.  Describe any differences in quality of the data bank (e.g., variables with more or fewer missing values) that have occurred over time.  Describe any differences in quality of the data bank (e.g., variables with more or fewer missing values) that have occurred over time.  Describe any differences in quality of the data bank (e.g., variables with more or fewer missing values) that have occurred over time.  Describe of the data bank.  Can validity of the data in the data bank be veriables with more or fewe	Unit: days  January/ February/ March/ April/ May/ June/ July/ August/ September/ October/ November/ December  DDMMYYY Unit: days  No/yes Unit: years  Free text  Upload  Allow individual AMA format citations / URL to list of publications.  Takes values from F1.1  URL  Allow individual AMA format citations / URL to list of publications.	data model to extract this information directly from a data bank  Manual entry, in future implementations scripts or functions could work tog ether with a common data model to extract this information directly from a data bank  Manual entry  Automatically populated when the data bank ID is entered in F3.4 - Study - data sources and data banks  Manual entry  Automatically populated when an entry is made in F7.2-Study report,	

.Classified as internal/staff contractors by the European Medicines Agency			