

IMI2 821520 - ConcePTION

ConcePTION

WP7 – Information and data governance, ethics, technology, data catalogue and quality support

D7.6 Prototype of FAIR data catalogue-1st

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Document History

Version	Date	Description	Non-contributor reviewers (if applicable)
V0.1	10 Apr 2020	First Draft	Work Package 7 review
V0.2	29 Apr 2020	Second Draft	Managing Board review
V1.0	18 May 2020	Final Version	

Abstract/Executive Summary

The objective of this report is to summarize delivery of the first prototype of the FAIR data catalogue for the ConcePTION project.

The objective of this prototype of the data catalogue is to collect **summary level metadata on data sources** to aid ConcePTION partners in the identification of relevant data sources for the conduct of studies to generate evidence on the safety of medicines in pregnancy (i.e. data source catalogue). The design of this catalogue is based on the requirements analysis as delivered in D7.1 'User requirements and meta-data model for the FAIR data catalogue from WP1&2'.

In particular, the catalogue prototype consists of:

- Module for pregnancy case reports generated through pharmacovigilance, teratology or bespoke pregnancy research cohorts
 - Data model to capture pregnancy case report information from data access providers in a structured way
 - Survey tool with web forms for pregnancy case report data providers to describe these collections in a standardised way.
 - Query tool to enable the consortium to filter and search the collected metadata
- Module for population-based healthcare data
 - Data model to capture information from such data access providers in a structured way
 - Survey tool with web forms for to data providers to describe these collections in a standardised way.
 - Query tool to enable the consortium to filter and search the collected metadata

In the past months we have implemented these requirements into a fully functional catalogue that is ready for user testing. The coming months will be spent thoroughly evaluating the prototype. The results of this testing period will be reported in a next deliverable D7.9: Test report of FAIR data catalogue 1st. Meanwhile all test findings will be processed, and necessary modifications made in order to accept the prototype into production state to be used by WP1, WP2 and WP7. D7.9 will also provide details of the scale-up of the catalogue to capture information on a much larger number of datasources, specifically those identified through Deliverable 1.1.

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Introduction

As extensively reported in the deliverable D7.1, the objective of the ConcePTION data catalogue is to serve the needs of ConcePTION partners to identify relevant data access providers and data sources for the conduct of studies to generate evidence on the safety of medicines in pregnancy. It also aims to enable ConcePTION partners to manage and share metadata on the individual data items and their harmonisations as used in ConcePTION studies.

The current (first) prototype focuses on a subset of these requested features:

- For WP1, which deals with use of population-based healthcare data collected during routine care or for population-based surveillance, the objective of the catalogue is to identify the healthcare data sources that can be used for medication utilisation and medication safety studies in pregnancy. This was to be achieved by updating and transforming the existing EUROMediSAFE¹ inventory into a searchable form, focusing primarily on existing and new sources in the EU and adding available non-EU data sources. However, as outlined in D7.1, due to heterogeneity of data capture within the EUROMediSAFE inventory and the need to sustainably capture accurate information from datasources; the decision was made to base meta-data capture on a specially designed survey/questionnaire tool.
- For WP2, which deals with reported (women themselves or health care professionals) pregnancy cases collected through pharmacovigilance, teratology information services or bespoke research cohort, the objective is to determine the structure of a meta data catalogue for industry and publicly held data sources. The structure will be defined through a survey/questionnaire that can subsequently be sent to relevant stakeholders.

What is not yet in this prototype, and will be the objective for the next prototype version are the features requested by WP7:

- For WP7, which deals with the infrastructure, governance and ethical aspects of evidence generation from data, the objective is to create a Findable, Accessible, Interoperable and Reusable (FAIR) data source catalogue with specific search features that will be defined based on user requirements. The catalogue will use standard metadata models to make datasources findable, understandable, and provide access control for researchers. The metadata will define 3 levels: the organization (Data Access Provider - DAP), the data source(s) the DAP has access to, and the datasets (that we call 'tables') that are part of the datasource. The catalogue will also interface to a secure negotiation service to arrange data access when participating in ConcePTION studies, and a separate private site for simple analysis of data characterisation tables from participating DAPs, which can be used for feasibility services following authentication. The catalogue will initially be filled for data sources identified through and relevant to WP1 and 2 research needs. Maintaining the accuracy of the meta-data as well as expansion of datasources captured will be discussed as part of further updates to the catalogue (D7.7 and D7.15) and as part of longer-term sustainability discussions (WP8).
- Moreover, WP7 establishes a remote operating platform and common data models for analysing data that are located in many different organizations in a distributed fashion while securely sharing results of analyses in an aggregated form. WP7 aims to set up the workflow and architecture to make this happen. WP7 is tasked with the data harmonization and characterization of datasources for use in WP1 and WP2. WP7 and Data Access Providers (DAPs) will perform harmonization in two steps: a first structural harmonization will be

¹ <http://euromedicat.eu/EUROMediSAFE/EUROMediSAFEInventory>

conducted by the DAPs locally by extracting data required for ConcePTION studies, and transforming the content of that extraction into a syntactically harmonized common data model (CDM). Subsequently, on a study-by-study basis, data will be further harmonized into a semantically harmonized set of study variables. The data dictionary of original data and the Extract Transform and Load (ETL) scripts used for syntactic harmonization will need to be uploaded to the catalogue for transparency. The Catalogue will also need to provide space for recording of the processes and decisions for semantic harmonization, as well as the querying of results of the data characterization.

- Finally, the Catalogue will host the results of the Data Characterisation study and will organize these results in such a way that they can be queried by researchers to understand the detailed features of the data whose description is contained in the previous sections of the Catalogue.

Methods

Implementation using MOLGENIS framework

We implemented the software using MOLGENIS, an open source software framework to automatically generate bespoke scientific catalogues and web applications based on a custom defined data model. The system allows for creation of query user interfaces, a main menu, questionnaire/survey, create/edit/delete forms to allow curation of the data, and Excel based data import/export formats and programmatic interfaces. Manuals can be found at <http://molgenis.org> and scientific publications at <https://www.ncbi.nlm.nih.gov/pubmed/?term=molgenis>

Structured data model

Using MOLGENIS, we translated the requirements defined in Deliverable 7.1 into a relational database model. The data model consists of two main modules, one for the pregnancy case report data and one for population based healthcare data (including population based registry data). Each module contains a main table 'questionnaire' and a few dozen additional tables to contain code lists/lookup lists, etc. In total there are 76 tables and 368 columns. **See appendix 1** for full details.

We used iterative 'sprints' to refine the prototype in 3 week iterations

With the first draft of the prototype developed, we had regular sessions with WP1, WP2, and WP7 representatives discussing the data model, the visualisation of that model within MOLGENIS, and the design of the survey. The final iteration resulted in the prototype described in this report.

Results

The prototype can be viewed here:

<https://molgenis98.gcc.rug.nl/> (after user registration, PMO can grant access)

For both pregnancy case reports as well as for the population-based healthcare datasources DAP surveys we have created

- a survey tool to collect relevant metadata
- a query user interface for the consortium to view and filter the collected metadata

- a web form for DAPs to curate these metadata online

Below we will shortly describe each element. The FAIR principles are realised through standardising the capture of meta-data through the survey tools. Standardisation will enable future design modifications for users of the catalogue especially in terms of how they search (find) information. In addition, to maximize FAIRness there are also programmatic interfaces in REST and a Bulk upload format using Excel (not described in this report).

Overview

The landing page of the prototype provides direct access to the two surveys. In addition, the main menu provides access to the results using the option ‘result survey’

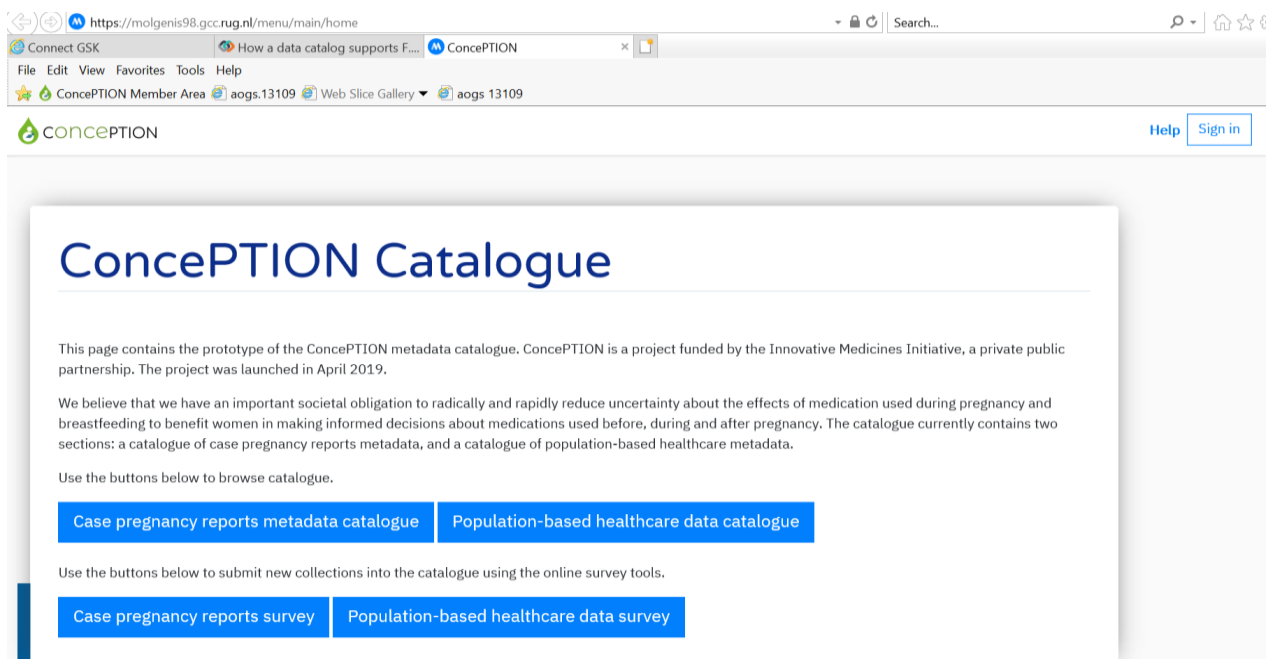


Figure 1: Landing page of the ConcePTION catalogue prototype

Pregnancy case reports data survey tool

We created an online survey tool to collect information about existing pregnancy case report data (derived from spontaneous reports, teratology information sources or bespoke pregnancy cohorts).

PREGNANCY PHARMACOVIGILANCE DATA SURVEY

The first section contains questions about your organisation.

Depending on the nature of the data you collect you can choose either "Spontaneous reports" or "Pregnancy cohort". In case you have multiple data collections, please complete the survey for the most important one and contact us. You will be sent an additional link to complete the questions for the other data collection.

2nd section - Characteristics

3th section - Variables

4th section - Coding and Classification

5th section - Quality Data

6th section - Linkage to other datasources

7th section - Usage data

8th section - Publications

9th section - Technical information

Try to answer questions as accurately as possible. If you do not know the exact answer, there are options for answering the question to reflect this. For some questions, it is possible to give more than one answer. These questions have little boxes instead of "radio buttons" (circles). Some questions are marked with an astrix (*), these fields need to be filled in.

If you have comments on the questionnaire, or want to add something about your answers, please write it down in the open field for comments at the end of the questionnaire.

Once again, thank you very much for your help!

[Continue questionnaire](#)

Figure 2: Screenshot of the starting screen*

*Please note for the second prototype wording will be harmonised for this section to reflect "pregnancy case reports" throughout rather than "pharmacovigilance data" in this example

[Back to start](#)

Chapter 1 of 6

DAP Organization Information

What is the official name of your organization as used in EU projects? *

What is the acronym of your organization that you use in EU projects?

Type of organisation *

- Academic institution
- Government agency
- Nonprofit organisation
- Other
- Pharmaceutical Industry
- Private organisation

[Select all](#) [Deselect all](#)

What country is your organisation located? *

In case of a dedicated website for the Organization, please provide the address (URL)

[Next chapter](#)

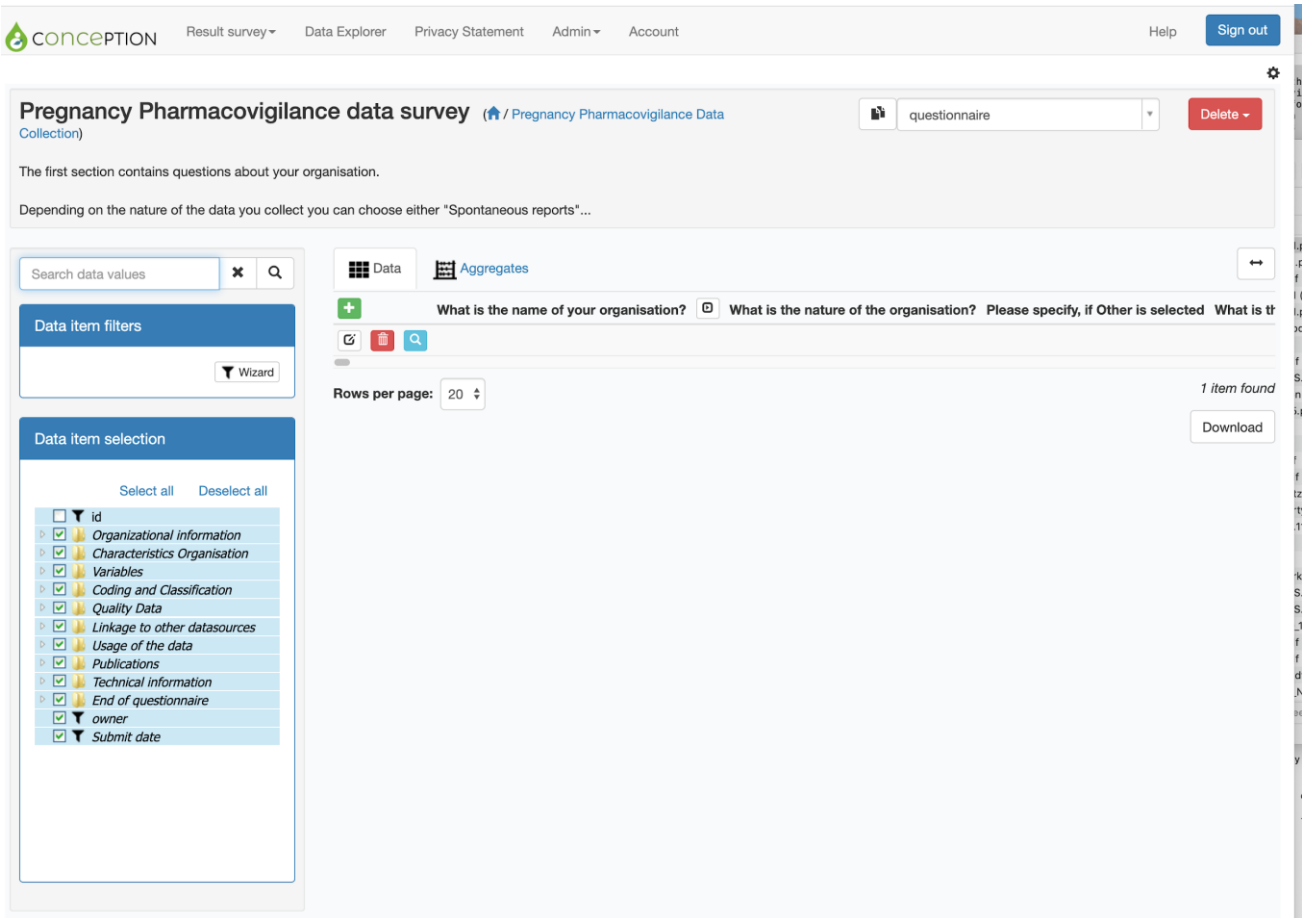
Chapters

- DAP Organization Information
- [Characteristics Datasource](#)
- Variables used in Datasource
- Governance & Data Quality
- Non-core data linkage
- Documentation

Figure 3: Screenshot of the first page of the survey:

Pregnancy case reports catalogue

We created an online results browser to enable consortium members to search and filter the results of the surveys.



The screenshot displays the 'Pregnancy Pharmacovigilance data survey' interface. At the top, there is a navigation bar with 'concePTION' logo, 'Result survey', 'Data Explorer', 'Privacy Statement', 'Admin', 'Account', 'Help', and 'Sign out' buttons. Below this, the main header includes the survey title, a breadcrumb trail, a dropdown menu set to 'questionnaire', and a 'Delete' button. The main content area contains instructions: 'The first section contains questions about your organisation.' and 'Depending on the nature of the data you collect you can choose either "Spontaneous reports"...'. A search bar is present with the text 'Search data values'. Below it are two panels: 'Data item filters' with a 'Wizard' button, and 'Data item selection' with 'Select all' and 'Deselect all' options. The 'Data item selection' panel lists various categories with checkboxes, all of which are checked. The main data view shows a table with one row: 'What is the name of your organisation?'. To the right of the table are 'Rows per page: 20' and '1 item found' indicators, along with a 'Download' button.

Figure 4: Pregnancy pharmacovigilance query tool (edit buttons only shown to curators)

Pregnancy case reports curation forms

For users with data management permission, we added the option to correct the survey data using online web forms. These users may simply use the 'pencil' button in above query tool to enter these forms.

PREGNANCY PHARMACOVIGILANCE DATA SURVEY

id *



Organizational information

What is the name of your organisation?

What is the nature of the organisation?

- Marketing Authorization Holder
- Other
- Patient Group or organisation
- National Pharmacovigilance centre/ regulatory agency
- Research organization/University
- Teratology Information Service

[Select all](#) [Deselect all](#)

What is the short version of the name of your organisation (acronym)?

What type of data do you collect in your organisation?

- None of the above
- Pregnancy Cohort
- Spontaneous Reports
- N/A

Does your organisation collect data or are you only accessing data collected by other organisations?

- Accessing data collected by others only
- Both collecting data combined with accessing data from other institutions
- Collecting data only
- N/A

Figure 5: Data curation forms.

Population-based healthcare data survey tool

We created an online survey tool to collect information about population-based healthcare data and population-linkable registry collections.

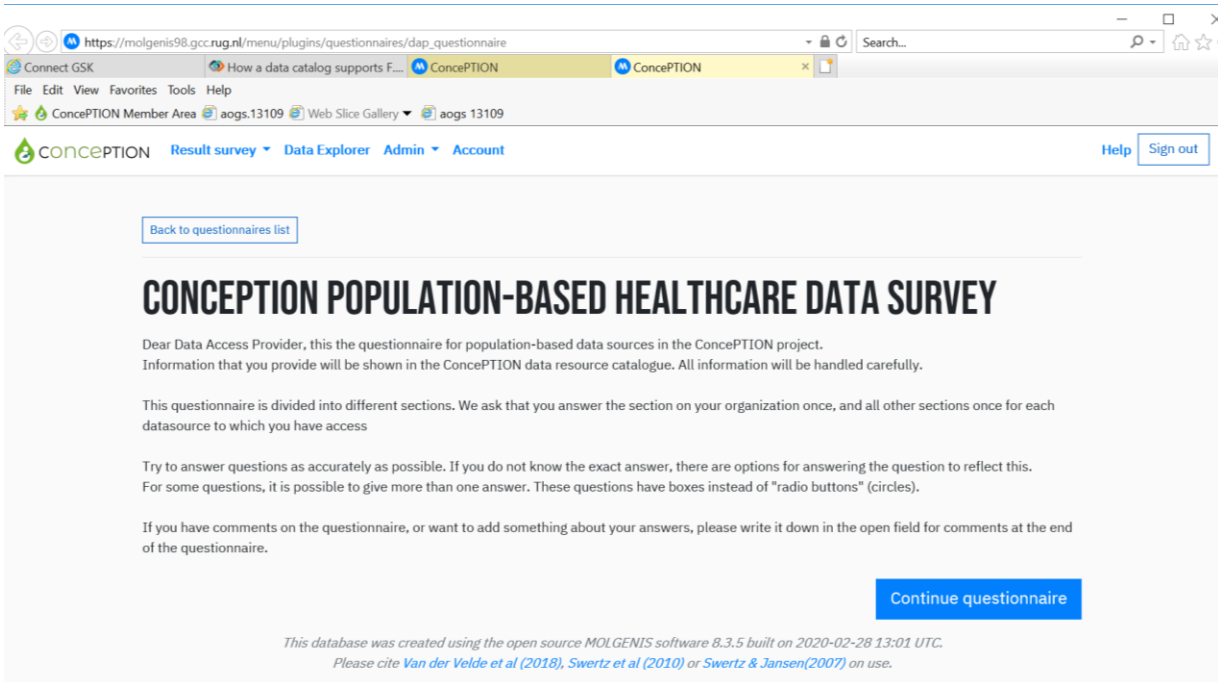


Figure 6: Screenshot of the starting screen for population-based healthcare data survey

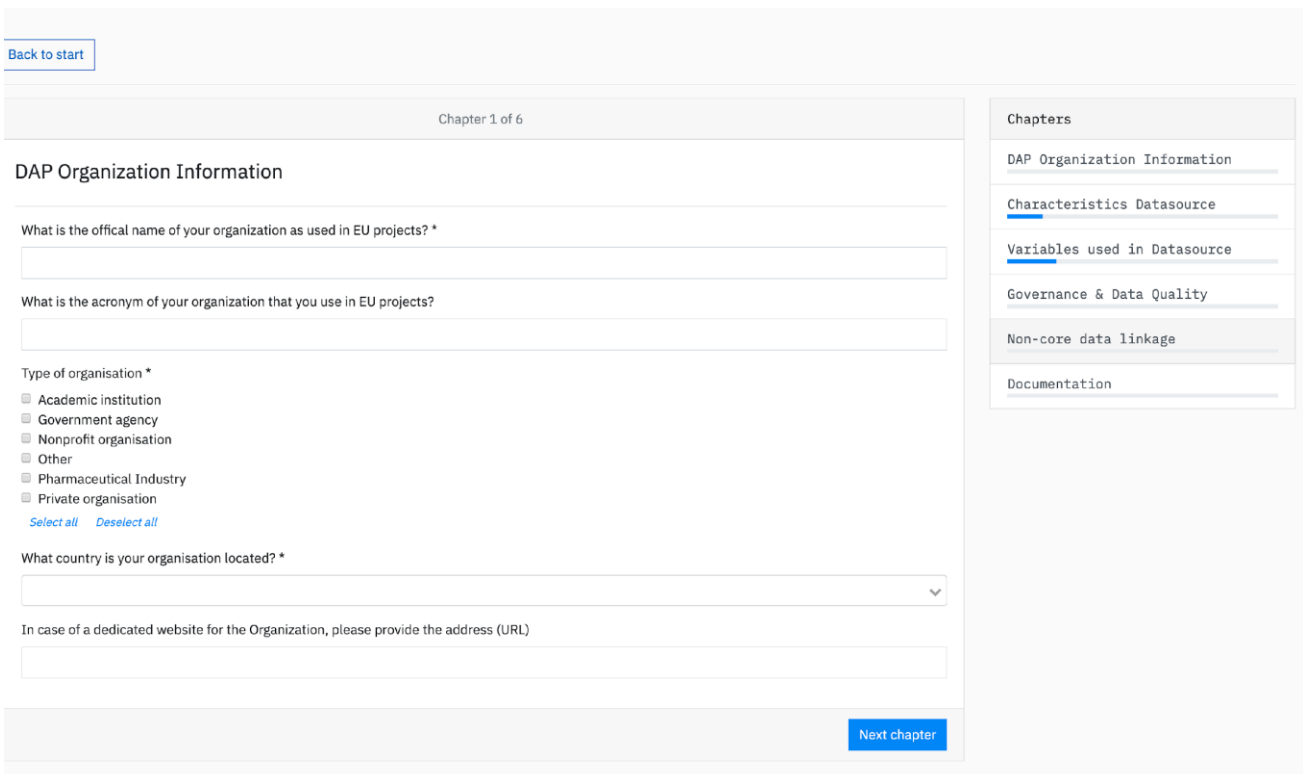


Figure 7: Screenshot of the first page of the survey for population-based healthcare data

Population based healthcare data survey query catalogue

We created an online results browser to enable consortium members to search and filter the results of the survey.

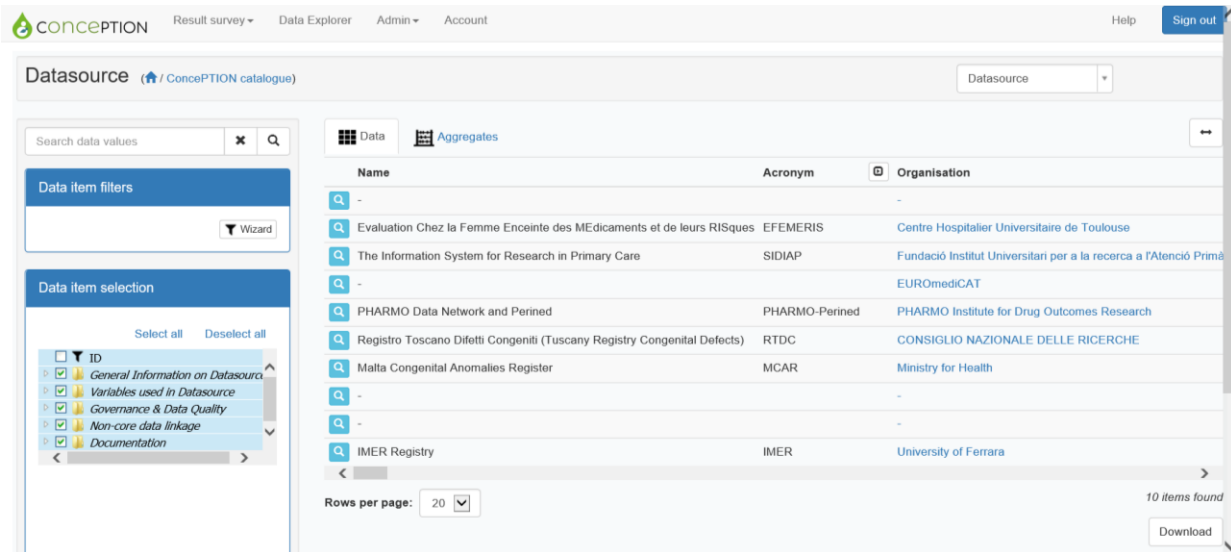


Figure 8: Population-based healthcare data query tool

Population-based healthcare data survey curation forms

For users with data management permission, we added the option to correct the survey data using online web forms. These users may use the ‘pencil’ button in the above query tool to enter these forms.

DAP Organization Information

What is the official name of your organization as used in EU projects?

What is the acronym of your organization that you use in EU projects?

Type of organisation

- Academic institution
- Government agency
- Nonprofit organisation
- Other
- Pharmaceutical Industry
- Private organisation

[Select all](#) [Deselect all](#)

What country is your organisation located?

In case of a dedicated website for the Organization, please provide the address (URL)

Figure 9: Data curation forms.

Conclusion & future work

The prototype is ready to be tested by both DAPs as well as researchers.

In the period leading up to the next deliverable we will organise two testing rounds; the results of which will be reported in D7.9: Test report of FAIR data catalogue 1st. In the first testing round, we will have one-on-one interviews with five test users (DAPs and researchers) identified from within the ConcePTION consortium (contact details provided by the project management office) to collect independent input that will either confirm the suitability of the current design or will lead to requests for change. Initial user testing will focus on the meta-data portion of the catalogue. We will then process the test results into a next version of the prototype. Optionally, we will repeat this testing procedure depending on the breadth of initial testing feedback. The aim of this phase is to produce a final version of this part of the catalogue.

In addition, we will start drafting the second prototype, which is aimed to deliver an additional component that aims to enable ConcePTION partners to **manage and share detailed metadata on the individual data items, their harmonisations and their use in ConcePTION studies** (i.e. study and data item catalogue), due to be delivered in D7.7 'Prototype of FAIR data catalogue - 2nd.

Appendix 1: data model

Below a partial export of the data structure used in the catalogue. Full model is described using MOLGENIS EMX data model format², using ‘entities’ to describe each table and ‘attributes’ to describe each column.

For a higher level view, the survey tools/questionnaires are found in D7.1

Entities (a.k.a. tables, 76 items)

Below listing of all tables. The data is split in two main modules: ‘conception’ containing pregnancy case report survey and population-based healthcare data survey. Most tables are code lists with structured survey answers.

Main tables

package	label
conception	questionnaire
dap	questionnaire

Code lists

package	label
conception	add_info_inquiry
conception	adv_outcome
conception	breastfeed_outc
conception	brfeed_outc_pregCoh
conception	CA_coding
conception	class_code
conception	code_drug
conception	code_indication
conception	coding_spont
conception	collect_Access
conception	collection_type
conception	comparison_group
conception	data_provider
conception	data_use
conception	death_spont
conception	delivery_compl_spont
conception	exposure_source
conception	exposure_spont
conception	follow_up
conception	info_exposure_drug
conception	info_exposure_type
conception	linkage_possible
conception	longterm_outcomes

² <https://molgenis.gitbooks.io/molgenis/content/guide-emx.html>

conception	lterm_dev_other
conception	nature_data
conception	organisation_type
conception	other_information
conception	outcome_source
conception	outcome_type_others
conception	out_long_term_dev
conception	out_lterm_health
conception	out_type_delivery
conception	out_type_pregcomp
conception	out_type_pregoutc
conception	population
conception	preg_compl_spont
conception	reporter_type
conception	restr_incl
conception	structure
conception	suspect_spont
conception	yesno
dap	addinfoOptions
dap	admission
dap	agegroup
dap	apliacationDate
dap	capture
dap	care
dap	charge
dap	codediagnosis
dap	codedrugs
dap	codeproces
dap	contraceptive
dap	country
dap	coverage
dap	datatype
dap	drugexpo
dap	drugsource
dap	europe
dap	eventsources
dap	expoinfo
dap	inhouse
dap	interviewTime
dap	link
dap	medication
dap	motherchild
dap	numberpart
dap	organisation_type
dap	outcomeinfo

dap	pregelements
dap	pregevents
dap	quality
dap	termination
dap	update
dap	yesno

Attributes (a.k.a. columns, 368 items)

Listing of all columns. 'Entity' is table, 'Name' is name of column, 'refEntityType' is reference to another table. Most references are for tables containing code lists.

entity	name	type	refEntityType
conception_add_info_inquiry	id	string	
conception_adv_outcome	id	string	
conception_breastfeed_outc	id	string	
conception_brfeed_outc_pregCoh	id	string	
conception_CA_coding	id	string	
conception_class_code	id	string	
conception_code_drug	id	string	
conception_code_indication	id	string	
conception_coding_spont	id	string	
conception_collect_Access	id	string	
conception_collection_type	id	string	
conception_comparison_group	id	string	
conception_data_provider	id	string	
conception_data_use	id	string	
conception_death_spont	id	string	
conception_delivery_compl_spont	id	string	
conception_exposure_source	id	string	
conception_exposure_spont	id	string	

conception_follow_up	id	string	
conception_info_exposure_drug	id	string	
conception_info_exposure_type	id	string	
conception_linkage_possible	id	string	
conception_longterm_outcomes	id	string	
conception_lterm_dev_other	id	string	
conception_nature_data	id	string	
conception_organisation_type	id	string	
conception_organisation_type	label	string	
conception_other_information	id	string	
conception_out_long_term_dev	id	string	
conception_out_lterm_health	id	string	
conception_out_type_delivery	id	string	
conception_out_type_pregcomp	id	string	
conception_out_type_pregoutc	id	string	
conception_outcome_source	id	string	
conception_outcome_type_others	id	string	
conception_population	id	string	
conception_preg_compl_spont	id	string	
conception_questionnaire	id	string	
conception_questionnaire	intro	compound	
conception_questionnaire	name	string	
conception_questionnaire	organisation_type	categoricalmref	conception_organisation_type
conception_questionnaire	organisation_other	text	
conception_questionnaire	acronym	string	
conception_questionnaire	collection_type	categorical	conception_collection_type

conception_questionnaire	organisation_objective_other	text	
conception_questionnaire	Data_CollectAcces	categorical	conception_collect_Access
conception_questionnaire	thank	text	
conception_questionnaire	characteristics	compound	
conception_questionnaire	section_1	compound	
conception_questionnaire	contact_content_sr	string	
conception_questionnaire	email_content_sr	email	
conception_questionnaire	aff_content_sr	string	
conception_questionnaire	contact_tech_sr	string	
conception_questionnaire	email_tech_sr	email	
conception_questionnaire	aff_tech_sr	string	
conception_questionnaire	pop_sr	categorical	conception_population
conception_questionnaire	startYear_sr	int	
conception_questionnaire	endYear_sr	int	
conception_questionnaire	size_sr	int	
conception_questionnaire	size_per_year_sr	int	
conception_questionnaire	rep_type_sr	categoricalmref	conception_reporter_type
conception_questionnaire	rep_type_oth_sr	text	
conception_questionnaire	reg_form_preg	categorical	conception_yesno
conception_questionnaire	reg_form_lact	categorical	conception_yesno
conception_questionnaire	use_sr	categoricalmref	conception_data_use
conception_questionnaire	use_oth_sr	text	
conception_questionnaire	cohort_1	compound	
conception_questionnaire	name_PregCohort	string	
conception_questionnaire	acronym_sr	string	
conception_questionnaire	contact_content_pc	string	

conception_questionnaire	email_content_pc	email	
conception_questionnaire	aff_content_pc	string	
conception_questionnaire	contact_tech_pc	string	
conception_questionnaire	Email_tech_pc	email	
conception_questionnaire	aff_tech_pc	string	
conception_questionnaire	obj_pc	categorical	conception_yesno
conception_questionnaire	website_pc	hyperlink	
conception_questionnaire	nature_data_pc	categoricalmref	conception_nature_data
conception_questionnaire	nature_pc	text	
conception_questionnaire	nature_PC_other	text	
conception_questionnaire	pop_pc	categorical	conception_population
conception_questionnaire	startYear_pc	int	
conception_questionnaire	endYear_pc	int	
conception_questionnaire	size_pc	int	
conception_questionnaire	size_per_year_pc	int	
conception_questionnaire	dataprovc_pc	categoricalmref	conception_data_provider
conception_questionnaire	prov_oth_pc	text	
conception_questionnaire	report_nvc_pc	categorical	conception_yesno
conception_questionnaire	report_nvc_yes	text	
conception_questionnaire	use_pc	categoricalmref	conception_data_use
conception_questionnaire	use_oth_pc	text	
conception_questionnaire	variables	compound	
conception_questionnaire	section_2	compound	
conception_questionnaire	exp_SR	categoricalmref	conception_exposure_spont
conception_questionnaire	exp_spec_SR	text	
conception_questionnaire	susp_SR	categoricalmref	conception_suspect_spont

conception_questionnaire	comed_SR	categorical	conception_yesno
conception_questionnaire	coding_sys_SR	categorical	conception_coding_spont
conception_questionnaire	coding_sys_dict_SR	text	
conception_questionnaire	dose_SR	categorical	conception_yesno
conception_questionnaire	exp_info_SR	categorical	conception_yesno
conception_questionnaire	outc_SR	categorical	conception_adv_outcome
conception_questionnaire	outc_oth_SR	categoricalmref	conception_outcome_type_oth ers
conception_questionnaire	death_SR	categoricalmref	conception_death_spont
conception_questionnaire	preg_compl_SR	categoricalmref	conception_preg_compl_spont
conception_questionnaire	deliv_compl_SR	categoricalmref	
conception_questionnaire	outc_bf_SR	categoricalmref	conception_breastfeed_outc
conception_questionnaire	oth_inf_SR	categoricalmref	conception_other_information
conception_questionnaire	Lt_SR	categorical	conception_longterm_outcome s
conception_questionnaire	cohort_2	compound	
conception_questionnaire	outc_source_PC	categoricalmref	conception_outcome_source
conception_questionnaire	restr_PC	categoricalmref	conception_restr_incl
conception_questionnaire	restr_spec_PC	text	
conception_questionnaire	datacol_PC	int	
conception_questionnaire	datacol_spec_PC	text	
conception_questionnaire	datacol_ad_PC	int	
conception_questionnaire	datacol_ad_spec_PC	text	
conception_questionnaire	reg_FU_PC	categoricalmref	conception_follow_up
conception_questionnaire	preg_FU_oth_PC	text	
conception_questionnaire	info_PC	categoricalmref	conception_add_info_inquiry
conception_questionnaire	info_spec_PC	text	

conception_questionnaire	info_source_PC	text	
conception_questionnaire	comp_PC	categoricalmref	conception_comparison_group
conception_questionnaire	comp_spec_PC	text	
conception_questionnaire	exp_PC	categoricalmref	conception_exposure_source
conception_questionnaire	inf_exp_type_PC	categoricalmref	conception_info_exposure_type
conception_questionnaire	inf_exp_drug_PC	categoricalmref	conception_info_exposure_drug
conception_questionnaire	pregoutc_PC	categoricalmref	conception_out_type_pregoutc
conception_questionnaire	pregoutc_type_PC	categoricalmref	conception_out_type_pregcomp
conception_questionnaire	outc_deliv_PC	categoricalmref	conception_out_type_delivery
conception_questionnaire	bf_PC	categorical	conception_yesno
conception_questionnaire	bf_outc_PC	categoricalmref	conception_brfeed_outc_pregCoh
conception_questionnaire	bf_outc_oth_PC	text	
conception_questionnaire	outc_oth_PC	categoricalmref	conception_outcome_type_others
conception_questionnaire	outc_LTdev_PC	categoricalmref	conception_out_long_term_dev
conception_questionnaire	outc_directAcc_PC	categoricalmref	conception_lterm_dev_other
conception_questionnaire	outc_LThealth_PC	categoricalmref	conception_out_lterm_health
conception_questionnaire	outc_LThealth_oth_PC	text	
conception_questionnaire	outc_LTdur_PC	text	
conception_questionnaire	inf_oth_PC	categoricalmref	conception_other_information
conception_questionnaire	coding	compound	
conception_questionnaire	section_3	compound	
conception_questionnaire	reg_use_SR	categorical	conception_yesno
conception_questionnaire	rep_exp_oth	text	
conception_questionnaire	code_outc_SR	categoricalmref	conception_class_code
conception_questionnaire	code_outc_oth_SR	text	

conception_questionnaire	qualdata_YN_SR	categorical	conception_yesno
conception_questionnaire	qualdata_SR	text	
conception_questionnaire	cohort_3	compound	
conception_questionnaire	reg_use_PC	categorical	conception_yesno
conception_questionnaire	rep_exp_oth_PC	text	
conception_questionnaire	code_drug_PC	categoricalmref	conception_code_drug
conception_questionnaire	code_drug_spec_PC	text	
conception_questionnaire	code_ind_PC	categoricalmref	conception_code_indication
conception_questionnaire	code_ind_spec_PC	text	
conception_questionnaire	code_outc_PC	categoricalmref	conception_class_code
conception_questionnaire	code_outc_spec_PC	text	
conception_questionnaire	code_CA_PC	categoricalmref	conception_CA_coding
conception_questionnaire	code_CA_spec_PC	text	
conception_questionnaire	quality	compound	
conception_questionnaire	section_4	compound	
conception_questionnaire	data_scr_SR	categorical	conception_yesno
conception_questionnaire	signal_SR	text	
conception_questionnaire	signal_LT_SR	text	
conception_questionnaire	extr_preg_SR	categorical	conception_yesno
conception_questionnaire	extr_preg_spec_SR	text	
conception_questionnaire	extr_lact_SR	categorical	conception_yesno
conception_questionnaire	extr_lact_proc_SR	text	
conception_questionnaire	cohort_4	compound	
conception_questionnaire	datascr_PC	categorical	conception_yesno
conception_questionnaire	signal_PC	text	
conception_questionnaire	update_freq_PC	string	

conception_questionnaire	qualdata_PC	text	
conception_questionnaire	preg_extr_PC	categorical	conception_yesno
conception_questionnaire	preg_proc_PC	text	
conception_questionnaire	bf_extr_PC	categorical	conception_yesno
conception_questionnaire	bf_proc_PC	text	
conception_questionnaire	linkage	compound	
conception_questionnaire	section_5	compound	
conception_questionnaire	rep_exp_EMA_SR	categorical	conception_yesno
conception_questionnaire	rep_exp_WHO_SR	categorical	conception_yesno
conception_questionnaire	rep_exp_NPV_SR	categorical	conception_yesno
conception_questionnaire	rep_exp_oth_SR	text	
conception_questionnaire	cohort_5	compound	
conception_questionnaire	link_PC	categoricalmref	conception_linkage_possible
conception_questionnaire	link_spec_PC	text	
conception_questionnaire	link_source_PC	text	
conception_questionnaire	usage	compound	
conception_questionnaire	section_6	compound	
conception_questionnaire	data_av_SR	categorical	conception_yesno
conception_questionnaire	perm_SR	text	
conception_questionnaire	appl_forms_SR	string	
conception_questionnaire	proc_times_SR	text	
conception_questionnaire	guidel_SR	string	
conception_questionnaire	cohort_6	compound	
conception_questionnaire	avail_PC	categorical	conception_yesno
conception_questionnaire	perm_PC	text	
conception_questionnaire	financ_PC	text	

conception_questionnaire	proc_times_PC	text	
conception_questionnaire	time_lag_PC	text	
conception_questionnaire	guidel_PC	string	
conception_questionnaire	applform_PC	string	
conception_questionnaire	publications	compound	
conception_questionnaire	section_7	compound	
conception_questionnaire	keypub_SR	text	
conception_questionnaire	cohort_7	compound	
conception_questionnaire	keypub_PC	text	
conception_questionnaire	technical	compound	
conception_questionnaire	section_8	compound	
conception_questionnaire	struct_SR	categorical	conception_structure
conception_questionnaire	struct_oth_SR	text	
conception_questionnaire	update_freq_SR	text	
conception_questionnaire	storageTime_SR	text	
conception_questionnaire	code_upd_SR	text	
conception_questionnaire	datamodel_SR	text	
conception_questionnaire	cohort_8	compound	
conception_questionnaire	data_entry_system_PC	text	
conception_questionnaire	storageTime_PC	text	
conception_questionnaire	security_PC	text	
conception_questionnaire	code_upd_PC	text	
conception_questionnaire	struct_PC	categorical	conception_structure
conception_questionnaire	struct_oth_PC	text	
conception_questionnaire	datamodel_PC	string	
conception_questionnaire	other_cohort	categorical	conception_yesno

conception_questionnaire	other_cohort_yes	text	
conception_questionnaire	end	compound	
conception_questionnaire	section_9	compound	
conception_questionnaire	cohort_9	compound	
conception_reporter_type	id	string	
conception_restr_incl	id	string	
conception_structure	id	string	
conception_suspect_spont	id	string	
conception_yesno	id	string	
dap_addinfoOptions	id	string	
dap_admission	id	string	
dap_agegroup	id	string	
dap_appliacationDate	id	string	
dap_capture	id	string	
dap_care	id	string	
dap_charge	id	string	
dap_codediagnosis	id	string	
dap_codedrugs	id	string	
dap_codeproces	id	string	
dap_contraceptive	id	string	
dap_country	id	string	
dap_coverage	id	string	
dap_datatype	id	string	
dap_drugexpo	id	string	
dap_drugsource	id	string	
dap_europe	id	string	

dap_europe	name	string	
dap_eventsources	id	string	
dap_expoinfo	id	string	
dap_inhouse	id	string	
dap_interviewTime	id	string	
dap_link	id	string	
dap_medication	id	string	
dap_motherchild	id	string	
dap_numberpart	id	string	
dap_organisation_type	id	string	
dap_outcomeinfo	id	string	
dap_pregelements	id	string	
dap_pregevents	id	string	
dap_quality	id	string	
dap_questionnaire	id	string	
dap_questionnaire	intro	compound	
dap_questionnaire	name	string	
dap_questionnaire	acronym	string	
dap_questionnaire	organisation_type	categoricalmref	dap_organisation_type
dap_questionnaire	organisation_other	text	
dap_questionnaire	organisation_europe	xref	dap_europe
dap_questionnaire	organisation_website	hyperlink	
dap_questionnaire	characteristics	compound	

dap_questionnaire	datasource_name	string	
dap_questionnaire	datasource_website	string	
dap_questionnaire	datasource_acronym	hyperlink	
dap_questionnaire	datasource_country	categoricalmref	dap_country
dap_questionnaire	datasource_europe	categoricalmref	dap_europe
dap_questionnaire	datasource_language	string	
dap_questionnaire	datasource_coverage	categoricalmref	dap_coverage
dap_questionnaire	datasource_cov_other	text	
dap_questionnaire	datasource_agegroup	categoricalmref	dap_agegroup
dap_questionnaire	datasource_type	categoricalmref	dap_datatype
dap_questionnaire	datasource_type_other	text	
dap_questionnaire	datasource_care	categoricalmref	dap_care
dap_questionnaire	datasource_care_other	text	
dap_questionnaire	datasource_capture	categoricalmref	dap_capture
dap_questionnaire	datasource_capture_other	text	
dap_questionnaire	datasource_selfReported	categorical	dap_yesno
dap_questionnaire	datasource_admission	categoricalmref	dap_admission
dap_questionnaire	datasource_admission_other	text	
dap_questionnaire	datasource_update	categoricalmref	dap_update
dap_questionnaire	datasource_update_other	text	
dap_questionnaire	datasource_modifydate	date	
dap_questionnaire	datasource_startcov	int	
dap_questionnaire	datasource_endcov	string	
dap_questionnaire	datasource_totalnumber	categorical	dap_numberpart
dap_questionnaire	datasource_numberperyear	categorical	dap_numberpart
dap_questionnaire	datasource_expinfo	categoricalmref	dap_expinfo

dap_questionnaire	datasource_interviewtime	categoricalmref	dap_interviewTime
dap_questionnaire	datasource_medication	categoricalmref	dap_medication
dap_questionnaire	datasource_contraceptive	categoricalmref	dap_contraceptive
dap_questionnaire	datasource_termination	categoricalmref	dap_termination
dap_questionnaire	datasource_outcomeinfo	categoricalmref	dap_outcomeinfo
dap_questionnaire	datasource_codeproces	categoricalmref	dap_codeproces
dap_questionnaire	datasource_codeproces_other	text	
dap_questionnaire	datasource_codedrugs	categoricalmref	dap_codedrugs
dap_questionnaire	datasource_codedrugs_other	text	
dap_questionnaire	datasource_codediagnosis	categoricalmref	dap_codediagnosis
dap_questionnaire	datasource_codediagnosis_other	text	
dap_questionnaire	variables	compound	
dap_questionnaire	variable_drugexpo	categoricalmref	dap_drugexpo
dap_questionnaire	variable_drugexpo_other	text	
dap_questionnaire	variable_drugsource	categoricalmref	dap_drugsource
dap_questionnaire	variable_inHouse7	categoricalmref	dap_inhouse
dap_questionnaire	variable_submissionTime7	categorical	dap_applicationDate
dap_questionnaire	variable_drugsource_other	text	
dap_questionnaire	variable_indication	categorical	dap_yesno
dap_questionnaire	variable_inHouse1	categoricalmref	dap_inhouse
dap_questionnaire	variable_applicationDate1	categorical	dap_applicationDate
dap_questionnaire	variable_breastfeed	categorical	dap_yesno
dap_questionnaire	variable_inHouse3	categoricalmref	dap_inhouse
dap_questionnaire	variable_applicationDate3	categorical	dap_applicationDate
dap_questionnaire	variable_excl_breastfeed	categorical	dap_yesno
dap_questionnaire	variable_inHouse2	categoricalmref	dap_inhouse

dap_questionnaire	variable_appliacationDate2	categorical	dap_appliacationDate
dap_questionnaire	variable_academic	categorical	dap_yesno
dap_questionnaire	variable_inHouse	categoricalmref	dap_inhouse
dap_questionnaire	variable_appliacationDate	categorical	dap_appliacationDate
dap_questionnaire	variable_pregelements	categoricalmref	dap_pregelements
dap_questionnaire	variable_inhouseElement	categoricalmref	dap_inhouse
dap_questionnaire	variable_submissionTime	categorical	dap_appliacationDate
dap_questionnaire	variable_pregevents	categoricalmref	dap_pregevents
dap_questionnaire	variable_inHouse5	categoricalmref	dap_inhouse
dap_questionnaire	variable_submissionTime5	categorical	dap_appliacationDate
dap_questionnaire	variable_eventsources	categoricalmref	dap_eventsources
dap_questionnaire	variable_inHouse6	categoricalmref	dap_inhouse
dap_questionnaire	variable_submissionTime6	categorical	dap_appliacationDate
dap_questionnaire	variable_eventsources_other	text	
dap_questionnaire	gov	compound	
dap_questionnaire	gov_coreData	categoricalmref	dap_inhouse
dap_questionnaire	gov_policy	categorical	dap_yesno
dap_questionnaire	gov_committee	categorical	dap_yesno
dap_questionnaire	gov_addinfo	categorical	dap_yesno
dap_questionnaire	gov_addinfoOptions	categoricalmref	dap_addinfoOptions
dap_questionnaire	gov_addinfoOptions_other	text	
dap_questionnaire	gov_restrictions	categorical	dap_yesno
dap_questionnaire	gov_restrictions_yes	text	
dap_questionnaire	gov_charge	categorical	dap_charge
dap_questionnaire	gov_processTime	categorical	dap_appliacationDate
dap_questionnaire	gov_quality	categoricalmref	dap_quality

dap_questionnaire	link	compound	
dap_questionnaire	handle_linkage	categorical	dap_yesno
dap_questionnaire	handle_linkage_yes	text	
dap_questionnaire	handle_linkage_variable	text	
dap_questionnaire	handle_link	categoricalmref	dap_link
dap_questionnaire	handle_link_yes	text	
dap_questionnaire	handle_charge	categorical	dap_charge
dap_questionnaire	handle_application	categorical	dap_applicationDate
dap_questionnaire	handle_inHouse	categorical	dap_yesno
dap_questionnaire	handle_policy	categorical	dap_yesno
dap_questionnaire	handle_committe	categorical	dap_yesno
dap_questionnaire	doc	compound	
dap_questionnaire	doc_publication	text	
dap_termination	id	string	
dap_update	id	string	
dap_yesno	id	string	