

## Module explainer: Term Collections

HaloPV Term Collections provides the ability to create and maintain lists of dictionary terms for consistent retrieval. These collections can consist of terms from MedDRA and WHO Drug dictionaries. The terms can be selected at any level of these dictionaries.

In the Medical Event Term Collection, the user can search and pick medical terms of interest and add them to their event term collection at any hierarchy level. In this example, the search finds all terms containing the word diabetic across the MedDRA hierarchy. The user then selected a combination of Preferred Terms and Higher Level Terms. The user also excluded terms.

The screenshot displays the 'Medical Event Term Collections' interface. The 'Name' field is 'Diabetes complications'. The 'Version' is '27.1' and the 'Language' is 'English (EN)'. The 'Record ID' is '33060649' and the 'Revision' is '1'. The 'MedDRA Dictionary' tab is active, showing a search for 'diabetic'. The results table lists terms like 'Diabetic complications', 'Diabetic complications NEC', 'Diabetic endocrinopathy', etc., with columns for Term, Level, Code, and Path (SOC). The 'Collection' panel on the right shows 'Included terms' (Diabetic complications, Diabetic complications NEC, Diabetic endocrinopathy, etc.) and 'Excluded terms' (Diabetic footpathology).

In the Product Term Collection, the user can make selections from the ATC hierarchy, WHO Drug Dictionary's Standard Drug Groupings, and individual products. Terms can also be excluded.

The screenshot displays the 'Product Term Collections' interface. The 'Name' field is 'Statin myopathy'. The 'Version' is 'GLOBALC3Mar24' and the 'Language' is 'English (EN)'. The 'Record ID' is '33060651' and the 'Revision' is '1'. The 'ATC Tree' tab is active, showing a search for 'Statin myopathy'. The results table lists terms like 'ALLIUM SATIVUM; CHROMIUM; LOVASTATIN; NICOTINAMIDE; PHYTOSTEROLS NOS; URIDECARENONE; VITAMIN E NOS', etc., with columns for Term, Code, and Path. The 'Collection' panel on the right shows 'Included terms' (HMG CoA reductase inhibitors, EZETIMIBE; ROSUVASTATIN, etc.) and 'Excluded terms' (ROSUVASTATIN, ROSUVASTATIN CALCIUM, etc.).

*Why use this module?*

Term Collections offer a consistent repeatable way of retrieving cases. This can be helpful when working, for example, with a complex medical concept that needs a precise definition that is not captured by a single MedDRA term nor SMQ. Once defined, the Medical Event Term Collection can be used in reporting, for example, to retrieve cases containing any one of the terms found in the collection.

## Feature highlights

A simple workflow supports defining the attributes of the collection.

The screenshot shows the 'Medical Event Term Collection' interface. The title bar reads 'Gait disturbances (Standard) CMQ -'. Below the title bar, there are two tabs: 'Term Collection Attributes' and 'MedDRA Tree Builder'. The 'Term Collection Attributes' tab is active. It contains several input fields: 'Query Type' (CMQ), 'Category' (Standard), 'Name' (Gait disturbances), 'Concatenated Name' (Gait disturbances (Standard) CMQ), 'Description' (This collection includes an HLT plus several PTs), 'Source' (Regulatory Department), 'MedDRA Version' (271), 'Language' (EN), 'Record ID' (34839635), and 'Revision no.' (1). There are 'Save' and 'Return' buttons in the top right corner.

The associated dictionary supports searching capabilities. Shown here is the MedDRA Tree Builder:

The screenshot shows the 'MedDRA Dictionary' interface with the 'MedDRA Queries' tab selected. The 'Selected Query Details' tab is also visible. The search results are displayed in a table with columns: Term, Primary/Sec, Level, Code, and Path (SOC). The search term 'gait' is entered in the search bar. The results show a hierarchy of terms related to gait, with 'gait' selected. The table is as follows:

Term	Primary/Sec	Level	Code	Path (SOC)
gait	X	✓	✓	✓ X
General disorders and administration site conditions		SOC	10018065	10018065
General system disorders NEC		HLGT	10018073	10018065
Gait disturbances		HLT	10017578	10018065
Investigations		SOC	10022891	10022891
Neurological, special senses and psychiatric investigations		HLGT	10029295	10022891
Neurologic diagnostic procedures		HLT	10029285	10022891
Tandem gait test	Primary	PT	10058559	10022891
Tandem gait test abnormal	Primary	PT	10058560	10022891
Tandem gait test normal	Primary	PT	10058561	10022891
Nervous system disorders		SOC	10029205	10029205
Movement disorders (incl parkinsonism)		HLGT	10028037	10029205
Parkinson's disease and parkinsonism		HLT	10034005	10029205
Parkinsonian gait	Primary	PT	10056242	10029205
Propulsive gait	Secondary	PT	10082328	10029205
Neurological disorders NEC		HLGT	10029305	10029205
Neurological signs and symptoms NEC		HLT	10029306	10029205

Selections are made by dragging and dropping:

The screenshot displays the MedDRA Dictionary interface. On the left, the 'MedDRA Dictionary' tab is active, showing a search for 'gait'. The 'Selected Query Details' tab shows the query results, including terms like 'General system disorders NEC', 'Gait disturbances', 'Decreased gait velocity', 'Gait deviation', 'Gait disturbance', 'Gait instability', 'Propulsive gait', 'Investigations', 'Neurological, special senses and psychiatric investigations', 'Neurologic diagnostic procedures', 'Tandem gait test', 'Tandem gait test abnormal', 'Tandem gait test normal', 'Nervous system disorders', and 'Movement disorders (incl parkinsonism)'. On the right, the 'Collection' tab shows a list of included terms, including 'Gait disturbances', 'Tandem gait test', 'Tandem gait test abnormal', 'Tandem gait test normal', 'Gait spastic', 'Parkinsonian gait', and 'Gait apraxia'. The 'Excluded terms' section is empty.

Term Collections allow for higher level terms to be selected and individual terms to be excluded.

The screenshot displays the MedDRA Dictionary interface. On the left, the 'MedDRA Dictionary' tab is active, showing a search for 'Angiodemas excl. intestinal'. The 'Selected Query Details' tab shows the query results, including terms like 'wheezing', 'Peripheral swelling', 'Visceral oedema', 'Hypersensitivity', 'Localised oedema', 'Cross sensitivity reaction', 'Peripheral oedema neonatal', 'Obstructive airways disorder', 'Oedema peripheral', 'Oedema', 'Oedema mouth', 'Scrotal swelling', 'Suffocation feeling', 'Oculorespiratory syndrome', 'Periorbital oedema', 'Breast oedema', 'Circumoral swelling', and 'Intestinal angioedema'. On the right, the 'Collection' tab shows a list of included terms, including 'Angioedema (SHQ)'. The 'Excluded terms' section shows 'Intestinal angioedema'.

## Pre-configured workflows

There are two pre-configured workflows:

Medical Event Term Collections

Product Term Collections

Each supports defining the attributes and terms of a collection. When satisfied, the user completes the workflow.

A 'flattened' list of constituent terms, at the Preferred Term level for MedDRA and at the Preferred Drug Name level for WHO Drug, is maintained with each collection.

## *What can be configured in the module?*

HaloPV, including the Term Collections, is extremely configurable. While the module comes with pre-configured workflows for a functional starting point, it is possible to enhance and tailor the application to support organizational needs in the most optimal way.

The following can be configured related to the Term Collections module:

- › Specific types of medical event or product term collections
- › Workflow name and order, worklist design, setup record types etc.
- › Workflow tasks, task order, including assignment to roles, form actions as well as functionality links.
- › Workflow rules for conditional routing of collections.
- › Validation rules for each field in the forms.
- › All dropdown (list) values in forms.
- › Entity (organizational) ownership to collections for segregation of collection records.
- › Users and user details, such as email and experience level and assigned roles.
- › Unblinding rights, workflow manager rights and management rights.
- › AI-thresholds for predictions to allow for confidence-based acceptance or rejection.
- › Keyword for tagging to case records and scripted auto-tagging based on case information.
- › Duplicate search composition and keyword weights.
- › Templates for emails, letters and reports, based on MS-Word, PDF or HTML.
- › Scheduling of activities, such as multiple email follow-up attempts.
- › Task timelines, KPIs and notifications of tasks upon task initiation or days to completion.

### *Configuration, not customization*

HaloPV is big on configurability. Not customization. In fact, the implementation team can help configure the system and provide advice as to how to optimize the use of the platform, without breaking the boundaries of what is considered as industry standard.

### *Frequent validated releases of the platform*

In order to meet customer needs, there is a HaloPV release and validation methodology that includes bi-annual versions with new innovation, optimizations, bugfixes etc. Subscribing customers can get new versions along with a comprehensive validation package to document it.

### *API driven*

HaloPV can be integrated to or migrate data from any systems by number of standard APIs that are modern REST based tools.

Contact for more information: