

## 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 shows the 'Medical Event Term Collections' interface. The search term is 'diabetic'. The results table shows various terms under 'Diabetic complications' and 'Diabetic complications NEC'. The 'Collection' section shows 'Included terms' such as 'Diabetic complication cardiovascular' and 'Diabetic complications NEC', and 'Excluded terms' like 'Diabetic footpathy'.

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 shows the 'Product Term Collections' interface. The search term is 'Statin myopathy'. The results table shows various statin products under 'ALLIUM SATIVUM; CHROMIUM; LOVASTATIN; NICOTINAMIDE; PHYTOSTEROLS NOS; UBIDECARENONE; VITAMIN E NOS'. The 'Collection' section shows 'Included terms' such as 'HMG CoA reductase inhibitors' and 'FISH OIL; LOVASTATIN', and 'Excluded terms' like 'ROSUVASTATIN'.

## 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' configuration page for 'Gait disturbances (Standard) CMQ'. The interface includes tabs for 'Term Collection Attributes' and 'MedDRA Tree Builder'. Key fields include:
 

- 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
- 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. A search for 'gait' has been performed, resulting in a list of terms. The 'gait' term is selected, and its details are shown in the table below.

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

Selections are made by dragging and dropping:

The screenshot shows the MedDRA Dictionary interface. On the left, a search for 'gait' has been performed, displaying a list of terms with their levels (Primary, SOC, HLT, PT) and codes. On the right, the 'Collection' panel is visible, showing 'Included terms' and 'Excluded terms'. The 'Included terms' list includes 'Gait disturbances', 'Tandem gait test', 'Tandem gait test abnormal', 'Tandem gait test normal', 'Gait spastic', 'Parkinsonian gait', and 'Gait apraxia'. The 'Excluded terms' panel is currently empty, showing 'No data found'.

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

The screenshot shows the MedDRA Dictionary interface for a pre-configured workflow. The search term is 'Angiodemas excl. intestinal'. The 'Collection' panel on the right shows 'Included terms' with 'Angioedema (SHQ)' selected and highlighted with a red circle. The 'Excluded terms' panel shows 'Intestinal angioedema' selected and highlighted with a red circle. A red arrow points from the 'Intestinal angioedema' term in the 'Excluded terms' list to the 'Angioedema (SHQ)' term in the 'Included terms' list.

## 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: