

Oracle Argus Safety

Usage of EDQM Routes of Administration (RoA) and Dose Forms (DF) Best Practices



Release 8.2.3.1

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The Oracle logo, consisting of a solid red square with the word "ORACLE" in white, uppercase, sans-serif font centered within it.

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Oracle Argus Safety Usage of EDQM Routes of Administration (RoA) and Dose Forms (DF) Best Practices, Release 8.2.3.1

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Preface

This preface contains the following sections:

- [Documentation accessibility](#)
- [Diversity and Inclusion](#)
- [Related resources](#)
- [Access to Oracle Support](#)

Documentation accessibility

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Diversity and Inclusion

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Related resources

For information about Oracle Argus patches, see [My Oracle Support](#).

All documentation and other supporting materials are available on the [Oracle Help Center](#).

Access to Oracle Support

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1

Revision history

Argus version	Description
8.2.3.1	First release

2

Introduction

This document provides best practices and recommendations to configure EDQM Routes of Administration (RoA) and Dose Forms (DF) set up for generating Post-Marketing and Clinical Trial reports using the E2B(R3) profile for EMA, MFDS and NMPA, with Argus Safety.

The International Council for Harmonisation (ICH) published the ICH User Guide: *Use of EDQM terminologies for Dose Forms and Routes of Administration for Individual Case Safety Reports in E2B(R3) message* on July 2020, version 1.1. The best practices and recommendations presented in this guide are based on this document and its guidelines.

The guidelines include the following:

- Details about EDQM API to access Standard Terms.
- Details on how to migrate E2B(R2) Routes of Administration text and Dose Form Text to the EDQM Standard Terms.
- Recommendations to send EDQM Term ID and version for Dose Formulation (DF) and Route of Administration (RoA).

Regional regulators published the following timelines for accepting EDQM RoA and DF terms:

- EMA timeline: June 30, 2022
- MFDS timeline: June 01, 2021
- NMPA timeline: July 01, 2022

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Upgrade preparations

Organizations need to plan to transition from the old dosage forms list to adopt Standard terms list provided by EDQM, according to the ICH User Guide: Use of EDQM terminologies for Dose Forms and Routes of Administration for Individual Case Safety Reports in E2B(R3) message July 2020 version 1.1.

- [General preparations](#)
ICH recommends providing the following data to represent EDQM terminology for Dose Form and Route of Administration.
- [Pre-upgrade preparations](#)
To ensure that the desired RoA and Formulations are available for case processing, organizations need to prepare with the following activities.
- [Post-upgrade](#)
After upgrade, take the following steps to ensure that the terms for the Routes of Administration and Formulation codelist are correct.
- [Periodic upgrade of EDQM Standard Term list](#)
Organizations need to update the safety systems regularly to get revised terms published by EDQM.

General preparations

ICH recommends providing the following data to represent EDQM terminology for Dose Form and Route of Administration.

The E2B(R3) DTD report populates the following data for Standard Terms for the ICH, EMA, MFDS and NMPA profiles:

Number	Element ID	Element Description
1	G.k.4.r.9.2b	Pharmaceutical Dose Form TermID
2	G.k.4.r.10.2b	Route of Administration TermID
3	G.k.4.r.11.2b	Parent Route of Administration TermID (in case of a parent child/fetus report)

The following elements are not required for Dose Form and Route of Administration as they are optional. Argus populates the following data in order to be consistent with codeSystem and codeSystemVersion implementation for HL7:

Number	Element ID	Element Description
1	G.k.4.r.9.2a	Pharmaceutical Dose Form TermID Version Date/Number
2	G.k.4.r.10.2a	Route of Administration TermID Version Date/Number

Number	Element ID	Element Description
3	G.k.4.r.11.2a	Parent Route of Administration TermID Version Date/Number

As part of the Argus release, the following actions touch on factory data:

- Factory data is provided for RoA and DF codelists in Argus to match EDQM Standard list as of July 2021.
- The Routes of Administration codelist in Argus is updated to incorporate the corresponding mapping of E2B(R2) Routes of Administration to EDQM Routes of Administration as published in the ICH User Guide.
- The formulation codelist is updated in Argus to incorporate the corresponding mapping of E2B(R2) Dose Formulations to EDQM Dose Formulations as published on the EAM website.
- Data cleanup for existing factory data for the Routes of Administration and Formulation codelists is done for the terms not used in E2B(R2), eVAERS, eMDR and PMDA reporting by setting the **Display** attribute as unchecked.

Pre-upgrade preparations

To ensure that the desired RoA and Formulations are available for case processing, organizations need to prepare with the following activities.

We advise organizations to review the Code list terms present in Argus for RoA and DF against Standard Term List and identify the terms that need to be available for data entry for your organization. This will ensure that the desired terms are available for data entry. The number of entries available for data entry during case processing are limited.

You can use the Case Form Console summary document provided as part of 8.2.3.1 eTRM to identify factory data and associated mapping to EDQM standard terms: *ArgusSafety8.2.3.1_CaseForm_Console_Updates_Summary.xls*.

Routes of Administration and Formulation Code List

Identify the terms that need to be available for data entry for your organization.



Note:

New terms added as part of the release are not available for data entry by default.

You can minimize the list further, if there are no reporting obligations to E2B(R2)/eVAERS/eMDR/PMDA, by marking the non-standard terms as `Display=unchecked`.

Post-upgrade

After upgrade, take the following steps to ensure that the terms for the Routes of Administration and Formulation codelist are correct.

1. Verify the terms in Console for Routes of Administration and Formulation Code List.
2. Check for duplicate terms in Routes of Administration and Formulation Code List by downloading the XLS file from the flex codelist: from the **Code lists** option, select **Flexible Data re-categorization**, then select **Flexible re-categorization** and then choose **ROUTE** and **FORMULATION**.
3. If you notice duplicate terms after upgrade (English text irrespective of case), then ensure that the English text is unique by using backend database updates and the **Display attribute of unused term** checkbox is unchecked.

 **Note:**

The Argus Console codelist displays a single entry for duplicate terms. Modifying the English text for a duplicate term is possible through Argus Console, where it updates text for one of the terms. It may not modify English text for a desired entry and you will have to ensure the internal ID associated with each term after English Text update.

4. Make sure all the terms intended for data entry have the **Display** attribute set as **Checked** and are available through the user interface.
5. Terms that need to be hidden for data entry should be marked as **Display=unchecked**.

Periodic upgrade of EDQM Standard Term list

Organizations need to update the safety systems regularly to get revised terms published by EDQM.

- Users should periodically check the [EDQM Standard Terms website](#) for any updates to the standard list. Instructions for checking dictionary updates are described in the [Check revisions for EDQM Standard Terms database](#) section.
- If there are any changes published by EDQM since the last **Load** process, download the required files using the EDQM API service and load the files in Argus database as described in the [Load an updated version of the Standard List](#) section.
- Review the email received from the EDQM Load utility containing updates made to the codelist. Verify the Argus code list attributes for the terms listed in that email.

Users should retain the factory data provided by Oracle. For business users this means that no additional data entry is required as it is already derived from the configuration.

 **Note:**

Make sure the **General Email** AG Service process is configured to send emails.

4

Configure the Routes of Administration flexible re-categorization codelists (NMPA Only)

The flexible re-categorization codelist is enhanced to include the new attribute **cn** to store Chinese terms for Routes of Administration and Dose Formulation. Chinese terms are provided only for the standard list of RoA and DF terms published by NMPA as part of the release. Make sure to add Chinese text for all the remaining terms for Routes of Administration and Dose Formulation. This is sent as free text in the E2B(R3) report for NMPA, if the term is not part of the standard term list.

Follow these steps to configure the **Routes of Administration** flexible re-categorization code lists:

1. Click **Code lists**, then click **Flexible Data re-categorization**.
2. On the **Flexible re-categorization** folder, select **ROUTE** from the **Code List Name** drop down.
3. Click **Search**. Note the **cn** column in the **ROUTE** table.



CODE	EN	E2B	CN	NCL_CODE
1	Articular use	001	关节内使用	C30192
10	Haemodialysis	010	血液透析	C30200
150	Intra-abdominal		腹腔内	C30220
100000	Beak dipping			
151	Intrabiliary		胆管内	C30224
152	Intrabronchial		支气管内	C30225
153	Intrabursal		滑液囊内	C30226
154	Intracardiac use		心脏内使用	C30228
155	Intracavitary		腔内	C30229
156	Intracranial, dental		颅内, 齿	C30217
157	Intracranial		颅内	C30236
158	Intraductal		导管内	C30240
159	Intraosseous		骨髓内	C30241
11	Int coop carrier	011	器械内	C30235
110	Intrasternal		胸骨内	C30242

4. Add Chinese text for non-standard terms, if it applies.
5. Save the changes.

Note:

The flexible re-categorization codelist does not validate the **cn** attribute. You are required to enter the information to limit the number of characters as per the ICH recommendation.

5

Configure the Dose Formulation flexible re-categorization codelists (NMPA only)

The flexible re-categorization codelist is enhanced to include the new attribute **cn** to store Chinese terms for Routes of Administration and Dose Formulation. Chinese terms are provided only for the standard list of RoA and DF terms published by NMPA as part of the release. Make sure to add Chinese text for all the remaining terms for Routes of Administration and Dose Formulation. This is sent as free text in the E2B(R3) report for NMPA, if the term is not part of the standard term list.

Follow these steps to configure the **Dose Formulation** flexible re-categorization code lists:

1. Click **Code lists**, then click **Flexible Data re-categorization**.
2. On the **Flexible re-categorization** folder, select **Formulation** from the **Code List Name** drop down.
3. Click **Search**. Note the **cn** column in the **Formulation** table.

Edit	Delete	Display	CODE	en	ja	NCL_CODE	cn
		<input checked="" type="checkbox"/>	1	Tablet	錠剤	C42999	片剂
		<input type="checkbox"/>	100	Injection, powder, for suspension	注入、粉末、懸濁液用	C42976	
		<input type="checkbox"/>	100000	Solution for spray			
		<input type="checkbox"/>	100001	Suspension for spray			
		<input type="checkbox"/>	100002	XYZ	XYZ-J		
		<input checked="" type="checkbox"/>	101	Injection, powder, for suspension, extended release	注入、粉末、懸濁液用、持続放出	C42977	
		<input checked="" type="checkbox"/>	102	Injection, powder, lyophilized, for liposomal suspension	注入、粉末、凍結乾燥、リポソーム懸濁液用	C42959	
		<input checked="" type="checkbox"/>	103	Injection, powder, lyophilized, for solution	注入、粉末、凍結乾燥、液剤用	C42957	
		<input checked="" type="checkbox"/>	104	Injection, powder, lyophilized, for suspension	注入、粉末、凍結乾燥、懸濁液用	C42956	
		<input checked="" type="checkbox"/>	105	Injection, powder, lyophilized, for suspension, extended release	注入、粉末、凍結乾燥、懸濁液用、持続放出	C42956	
		<input checked="" type="checkbox"/>	106	Injection, solution	注入、液剤	C42945	
		<input checked="" type="checkbox"/>	107	Injection, solution, concentrate	注入、液剤、濃縮	C42889	
		<input checked="" type="checkbox"/>	108	Injection, suspension	注入、懸濁液	C42995	
		<input checked="" type="checkbox"/>	109	Injection, suspension, extended release	注入、懸濁液、持続放出	C42926	
		<input checked="" type="checkbox"/>	11	Liquid	外用液剤	C42953	
		<input checked="" type="checkbox"/>	110	Injection, suspension, liposomal	注入、懸濁液、リポソーム	C42951	

4. Add Chinese text for non-standard terms, if applied.
5. Save the changes.

Note:

The flexible re-categorization codelist does not validate the **cn** attribute. You are required to enter the information to limit the number of characters as per the ICH recommendation.

6

Generate E2B(R3) reports for EMA, MFDS and NMPA

Follow these steps to create or process cases using EDQM terminology for Routes of Administration and Dose Form:

1. Book-in a case with the information received according to source documents.
2. Verify if **Dose Formulation and Routes of Administration** is part of the EDQM Standard List.
3. Save the case and ensure all the mandatory data required for E2B(R3) submission are entered.
4. Perform **Auto-scheduling** so that the system schedules an E2B report to the agency using 3.0 DTD Profile.
5. Click the **Draft** link to preview the report in XML view.

The <G.k.4.r.9.2b> element is populated with the value indicating the corresponding **EDQM TERM ID** associated with Dose Formulation.

The <G.k.4.r.10.2b> and <G.k.4.r.11.2b> elements are populated with the values that indicate the corresponding **EDQM TERM ID** associated with Routes of Administration.

The EDQM details data are embedded within the drug block pertaining to the product as below.

```
<!--G.k.4.r.10.2a: Route of Administration TermID Version Date / Number-->
<!--G.k.4.r.10.2b: Route of Administration TermID-->
<routeCode code="ROA-20001000" codeSystem="0.4.0.127.0.16.1.1.2.6"
codeSystemVersion="1">
  <originalText>Auricular use</originalText>
</routeCode>
<consumable typeCode="CSM">
  <instanceOfKind classCode="INST">
    <kindOfProduct classCode="MMAT" determinerCode="KIND">
      <!--G.k.4.r.9.1: Pharmaceutical form (Dosage form)-->
      <!--G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date /
Number -->
      <!--G.k.4.r.9.2b: Pharmaceutical Dose Form TermID -->
      <formCode code="BDF-0051" codeSystem="0.4.0.127.0.16.1.1.2.1"
codeSystemVersion="2">
        <originalText>Capsule</originalText>
      </formCode>
    </kindOfProduct>
  </instanceOfKind>
</consumable>
<inboundRelationship typeCode="REFR">
  <observation moodCode="EVN" classCode="OBS">
    <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
codeSystemVersion="2.0" />
```

```
<!--G.k.4.r.11.2a: Parent Route of Administration TermID
Version Date /
Number-->
<!--G.k.4.r.11.2b: Parent Route of Administration TermID-->
<value xsi:type="CE" code="ROA-20004000"
codeSystem="0.4.0.127.0.16.1.1.2.6" codeSystemVersion="1">
  <originalText>Dental use</originalText>
</value>
</observation>
</inboundRelationship>
```


7

Generate E2B(R3) reports for non-standard terms

Follow these steps to create and process cases using non-standard terms. These cases include terms that are not part of the EDQM terminology for Routes of Administration and Dose Form:

1. Book-in a case with the information received as per Source documents.
2. Verify that Dose Formulation and Routes of Administration are not part of the EDQM Standard List.
3. Save the case and ensure that all the mandatory data required for E2B(R3) submission are entered.
4. Perform Auto-scheduling so that the system schedules an E2B report to the agency using 3.0 DTD Profile.
5. Click the **Draft** link to preview the report in XML view.

The <G.k.4.r.9.1> element is populated with free text associated with Dose Formulation.

The <G.k.4.r.10.1> and <G.k.4.r.11.1> elements are populated with free text associated with Routes of Administration.

The EDQM details data are embedded within the drug block pertaining to the product as below:

```
<!--G.k.4.r.10.2a: Route of Administration TermID Version Date / Number-->
<!--G.k.4.r.10.2b: Route of Administration TermID-->
<routeCode>
  <originalText>Auricular use</originalText>
</routeCode>
<consumable typeCode="CSM">
  <instanceOfKind classCode="INST">
    <kindOfProduct classCode="MMAT" determinerCode="KIND">
      <!--G.k.4.r.9.1: Pharmaceutical form (Dosage form)-->
      <!--G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date /
Number -->
      <!--G.k.4.r.9.2b: Pharmaceutical Dose Form TermID -->
      <formCode>
        <originalText>Capsule</originalText>
      </formCode>
    </kindOfProduct>
  </instanceOfKind>
</consumable>
<inboundRelationship typeCode="REFR">
  <observation moodCode="EVN" classCode="OBS">
    <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
codeSystemVersion="2.0" />
    <!--G.k.4.r.11.2a: Parent Route of Administration TermID Version
Date / Number-->
```

```
<!--G.k.4.r.11.2b: Parent Route of Administration TermID-->  
<value xsi:type="CE">  
  <originalText>Dental use</originalText>  
</value>  
</observation>  
</inboundRelationship>
```

 **Note:**

If you already use a custom profile for reporting to EMA or MFDS, then you can recreate a new custom profile based on the respective template if you want to use updated mappings or other EDQM related settings. You might encounter issues during report generation if you try to re-use an existing profile without all changes set in the Out-of-the-box (OOTB) profile.

 **Note:**

E2B(R2), eVAERS, PMDAR3 do not populate **EDQM TERM ID**, but they populate data according to the existing logic.

8

EDQM Term List Loader utility

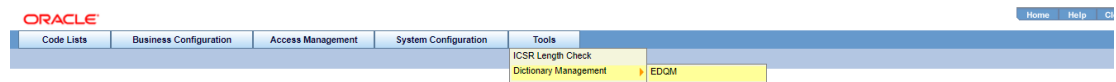
The Argus Console application provides the **EDQM** option for **Dictionary Management** on the **Tools** tab of the menu bar.

- [EDQM Term List Loader utility field descriptions](#)
The EDQM Term List Loader Utility can be used to load the EDQM Standard Terms database in Argus, to maintain a local repository for the EDQM Standard Terms database or to synchronize the Argus code list for Routes of Administration and Dose Forms.
- [Error and warning messages](#)
When you click the **Load** button, several error or validation messages can appear.

EDQM Term List Loader utility field descriptions

The EDQM Term List Loader Utility can be used to load the EDQM Standard Terms database in Argus, to maintain a local repository for the EDQM Standard Terms database or to synchronize the Argus code list for Routes of Administration and Dose Forms.

The Argus Console application provides the **EDQM** option for **Dictionary Management** on the **Tools** tab of the menu bar:



The EDQM Term List Loader Utility can be used to:

- Load the EDQM Standard Terms database in Argus.
- Maintain a local repository for the EDQM Standard Terms database.
- Synchronize the Argus code list for Routes of Administration and Dose Forms.

This utility needs to be used to load the standard dictionary provided by EDQM accessed through EDQM API.

The EDQM Term List Loader utility accepts the following inputs for the above fields:

- Dictionary File**
 Provide the ZIP file containing JSON files from the EDQM Standard Dictionary. Refer to the *Create a ZIP file with EDQM Standard List* section for details on how to create a ZIP file.

 **Note:**

We recommend you to follow the dictionary files naming convention.

- Argus Code List mapping to Concept Class**
 The data from **Route of Administration** and **Dose Formulation** fields indicate the EDQM concept class terms mappings to Argus Code list.
 Factory data are provided for these fields.
 The **Routes of Administration** codelist uses terms with ROA concept class.
 The **Dose Formulation** codelist uses terms with the following concept classes:
 - PDF - Pharmaceutical Dose Form
 - CDF - Combined Pharmaceutical Dosage Form
 - BDF - Basic Dose Form
 - PFT - Patient Friendly Term
 If a term belongs to multiple concept classes, EDQM Term ID is determined based on the order specified in this box. Factory data are provided considering the following priority: PDF, CDF, BDF, PFT.
 The user should not remove any concept class from the **Route of Administration** and **Dose Formulation** fields. Removing any class from this list may result in incorrect resolution of the EDQM Term ID reporting.
 If the users need to change the method of creating EDQM Term ID for duplicate terms, they can only reorder the class codes for Dose Formulation.
 The priority order will be changed only after successfully loading the new dictionary files.

- Notification Email Address**

The user provides the list of email addresses that will receive notifications regarding the status of EDQM Load process. The email contains changes done to Argus Code List such as new term addition, existing term updates, and term status changes.

When a user clicks the **Load** button, the EDQM standard dictionary loads in the local repository. If the system identifies any changes, the **Routes of Administration** and **Formulation** codelists are updated.

The following table describes possible updates to the EDQM Standard list and changes to the Argus codelist as part of the Load process:

#	EDQM Updates	Argus Code List updates for RoA/DF
1	Addition of new item	New term is added to the respective Argus codelist only if there isn't another matching term. The new term is marked as Display = un-checked and it is not available for data entry. The codelist administrator can modify the Display attribute in Console to make the term available for data entry. If there is an equivalent matching term present in the Argus codelist, that term is considered as part of EDQM Standard Term and no new codelist entry is added.
2	English term text revised	Existing term text updated with revised English text for the corresponding internal ID.
3	Status change for a term to Deprecated or Rejected	An invalid term is marked as Display = un-checked in Argus Code list and thus the term is not available for data entry. This is applicable to any term present on Argus Code list such as OOTB or custom entry. Your Code List administrator can modify the Display attribute in Console to make the term available for data entry.
4	Translation text updated for a term	No changes are applied to Argus.

- **Status**
The **Status** box is refreshed automatically, displaying the progression of the **Load** process.
- **Load process**
All changes made to the code list by the Load process are available in the **Utilities** tab, **Audit Log** option for review.

After a successful Load, an email is sent to all email addresses specified in the **Notification Email Address** field.

In case of any failure of the Load process, no changes are made to the Argus Code List.

Error and warning messages

When you click the **Load** button, several error or validation messages can appear.

#	Scenario	Error Type	Error Message	User Action
1	If you remove any of the concept class from the UI for which data is already loaded in Argus Code List and then click the Load button.	MessageBox	Cannot remove concept class that is already loaded in EDQM Standard List: <PDF, CDF,BDF,PFT>	In Dose Formulation enter this string and click the Load button: PDF, CDF, BDF, PFT.

#	Scenario	Error Type	Error Message	User Action
2	If a duplicate concept class is entered in the Concept Class input field and then you click the Load button.	MessageBox	<Route of Administration / Formulation> - Duplicate values are not allowed in concept class.	Make sure the strings separated by comma in Route of Administration and Dose Formulation are not duplicated in any of the boxes before you click the Load button.
3	If you enter the same concept class in both boxes and click the Load button.	MessageBox	Please make sure the concept class values are correct for each Code List.	Make sure the strings separated by a comma in Route of Administration and Dose Formulation are not duplicated in any of the boxes before you click the Load button.
4	If you enter an invalid email address in a list and click the Load button.	MessageBox	Please correct invalid email address(es): <email xyz><abc@>	Enter a valid email address before you click the Load button. Valid email format is: <i>abc@xyz.com</i> .
5	If an uncompressed file size exceed the limit of 1 GB, it is likely that the files are corrupted given that the ZIP file limit is 30MB.	MessageBox	ZIP file is invalid. Please check contents of the file and upload again.	Make sure the ZIP file (dictionary file) size is less than 1 GB. Reload the file before you click the Load button.
6	If you select a zip file that does not contain any JSON files and click the Load button. OR If you select a ZIP file that does not contain any of the concept class file for RoA and DF and click the Load button. The number of concept classes provided in UI for RoA and DF does not match the number of JSON files with term list included in ZIP file and you click the Load button.	MessageBox	Incorrect files provided in ZIP. Please make sure that the ZIP contains one file for each concept class.	Make sure the ZIP file contains one JSON file for each concept class, along with region and languages before you click the Load button. Refer to the Create ZIP file containing JSON files section for more information.
7	If you provide a ZIP file that contains multiple files with terms from the same concept class and you click the Load button.	MessageBox	Files with duplicate data is provided. Please make sure that the ZIP contains only one file for each concept class. Verify files: <file1.json> <file2.jspn>	Make sure the ZIP file contains one JSON file for each concept class, along with region and languages, before you click the Load button. Refer to the Creating a ZIP file with EDQM standard list section for more information.

#	Scenario	Error Type	Error Message	User Action
8	If you select a ZIP file that does not contain either or both configuration files for Languages and/or Regions and you click the Load button.	MessageBox	Configuration files are missing. Please make sure to include json files for Languages and Regions in ZIP file.	Make sure the ZIP file contains one JSON file for each concept class, along with region and languages, before you click the Load button. Refer to the Creating a ZIP file with EDQM standard list section for more information.
9	If the ZIP file contains a JSON file that is missing mandatory data and then you click the Load button.	MessageBox	Invalid JSON file. Please make sure to download the correct file from website. File is missing mandatory data. Element: <element_name from json> Filename: <file1.jsp>	Make sure the JSON files are correctly downloaded from the EDQM website and then uploaded before you click the Load button. Refer to the Download the EDQM standard list for Dose Formulation and Routes of Administration section.
10	If the .zip file contains a JSON file that is in an incorrect format and you click the Load button.	MessageBox	Invalid json file. Please make sure to download the correct file from website. Filename: <file1.jsp>	Make sure the JSON files are correctly downloaded from the EDQM website and then uploaded before you click the Load button. Refer to the Download the EDQM standard list for Dose Formulation and Routes of Administration section.
11	If you select a ZIP file containing a JSON file where a concept class string for the first term in the JSON file does not match with the concept class derived from the file name and you click the Load button.	MessageBox	Concept class derived from file name does not match with the terms from file. Concept Class: <concept class from first term> File Name: <filename.json>	Make sure the JSON files are correctly downloaded from the EDQM website and then uploaded before you click the Load button. Refer to the Download the EDQM standard list for Dose Formulation and Routes of Administration section.
12	If you select a ZIP file containing any file which could potentially harm the system and it is being deleted by the system's antivirus policy and thus it is not available for processing, and then you click the Load button.	MessageBox	Folder path does not exist. Please contact system administrator.	Check if the folder path for the provided ZIP file is valid and has access rights to the user account used by the Argus application.

#	Scenario	Error Type	Error Message	User Action
13	If you click the Load button while the dictionary is still loading by another user.	MessageBox	EDQM dictionary loading is already initiated by <user name>.	Contact <user name> on the status of EDQM Dictionary load or Refresh the web UI: from Console go to the Tools tab, then select from the dropdown Dictionary Management and then EDQM after a few minutes to view the status of a previous process run.
14	If you click the Load button and then click the Cancel button while EDQM Dictionary Load process is managing JSON files. At this stage, the process cannot be canceled since the JSON file is being validated. Once the JSON file validation is done, then you can cancel the process. OR If you click the Load and then click on the Cancel button while EDQM Dictionary Load process has processed JSON files and then updated the database code list tables (i.e. after Updating Argus Code List). At this stage, the process cannot be canceled.	Status	Load process cannot be canceled at this stage. Please try again later.	Visit or refresh the EDQM utility after a few minutes to view the status of a previous process run.
15	If you click the Load button while dictionary loading is already in process by the same or another user.	Status	EDQM dictionary loading is in progress. Initiated at: <DD-MON-YYYY HH:mm:ss> GMT	No action required by the user. This message represents information on the current status of the process.
16	If the Load process is canceled and you click the Cancel button again in another instance or if it is canceled by another user while the system is reverting the changes.	Status	Previous Load process is being canceled. Please try again later.	No action required by the user. This message represents information on the current status of the process.
17	If you click the Cancel button after clicking the Load button before the Code list update process is complete.	Status	Cancellation of EDQM Terms load is in progress.	No action required by the user. This message represents information on the current status of the process.
18	If a system error occurs during the Cancel process.	Status	Failed to cancel process. Please try again later.	No action required by the user. This message represents information on the current status of the process.

Additionally, the following messages are refreshed automatically based on the EDQM Term Load process progress. These messages are available only when you perform the Load process and then stay on the same UI. Refreshing the UI will clear the **Status** field.

#	Scenario	Message
1	User provides valid inputs and clicks the Load button.	EDQM Terms loading is in progress...
2	User describes the Validating files step during the Load process.	Validating dictionary files.
3	User describes the Creating local repository step during the Load process.	Creating EDQM local repository.
4	User describes the Updating Argus Code List for RoA step during the Load process.	Updating Argus Code List for RoA.
5	User describes the Updating Argus Code List for DF step during the Load process.	Updating Argus Code List for Dose Formulation.
6	After the Load process is successful.	EDQM Terms loaded successfully.
7	Email is sent with status.	Email sent.
<div data-bbox="711 835 755 877" data-label="Image"></div> <div data-bbox="760 835 841 869" data-label="Section-Header">Note:</div> <div data-bbox="760 894 967 1037" data-label="Text"> <p>The AG Service process General Email needs to be running to send an email.</p> </div>		
8	EDQM Term load failed. Any general code level or database exception.	EDQM Terms load failed.
9	EDQM Term load failed while processing JSON files.	Failure while processing JSON files.
10	Database access or a network error occurred during EDQM Load process.	Failure while initiating database updates.
11	User clicks the Cancel button while EDQM Load is in progress.	EDQM Terms load Cancel initiated.
12	If the EDQM Term load is successfully canceled after the user clicks the Cancel button.	EDQM Terms load is canceled.

9

Load an updated standard code list in a multi-tenant environment (CRO)

The Dictionary Management **EDQM** option has the following specifications:

- It is available to a default enterprise only.
- It performs system-level updates.
- It refreshes the code list for all tenants (enterprises) in an multi-tenant environment.

The CRO global administrator should use this tool to refresh all the tenant databases.

The **Notification Email Address** field from the EDQM utility provides email addresses for all the tenant organization codelist administrators. This field facilitates status email notifications, as a result of the Load process.

Each tenant organization should take actions to manage their own Argus code list attributes.

10

Add a new enterprise

When an administrator adds a new enterprise, a Global administrator needs to load the EDQM standard list to synchronize the Argus codelists by using the **EDQM** option for **Dictionary Management**, from the **Tools** tab of the Argus Console.

The Global administrator can download the latest dictionary files from the EDQM website or it can use previously downloaded files.

If a Clinical Research Organization (CRO) administrator has used previously downloaded files, the codelist will update only for new enterprises.

If a CRO admin has used a revised dictionary files, the existing enterprises and new enterprises will be updated as per the new dictionary files.



Note:

For newly added enterprises, the factory data provided by Argus release should be present prior to the Load process.

11

Create a ZIP file with EDQM standard list

- [Set up a user account with EDQM](#)
The following steps describe how to set up an EDQM account.
- [Download the EDQM standard list for Dose Formulation and Routes of Administration](#)
The following steps describe how to download the EDQM standard list for Dose Formulation and Routes of Administration.
- [Check revisions for the EDQM standard terms database](#)
The following steps describe how to check for any revisions published by EDQM since the last time your files were downloaded.

Set up a user account with EDQM

The following steps describe how to set up an EDQM account.

Before you begin, make sure you have a user account with API access privileges.

1. Access the [EDQM Customer Service Desk](#).
2. Log in using the credentials from the email with the subject line: *EDQM EPID registration*.
3. Request access to the Standard Database terms.
 - a. Go to the **Profile** menu option under **WELCOME <username>**.
 - b. **Accept** the terms for using API.
4. Verify that the **Help API** menu option is available under the **NEWS AND INFORMATION** link.

Download the EDQM standard list for Dose Formulation and Routes of Administration

The following steps describe how to download the EDQM standard list for Dose Formulation and Routes of Administration.

1. Access the EDQM Standard List at [EDQM standard list](#).
2. Log in using your credentials.
3. From the navigation menu options, choose: **NEWS AND INFORMATION** and then **HELP API**.
4. Scroll down to the **API StandardTerms** section.
5. Click the `/basic_data_by_class/{concept1}/{concept2}/{concept3}` link to expand it.
6. Get the JSON file for **BDFconcept**.

8. Get the JSON files for Languages and Regions. These files are required to verify and store translation data provided by EDQM.
 - a. Scroll down the same page and expand the `/languages` API by clicking the link associated with it.

GET `/languages`

Implementation Notes
Returns list of Language objects.

Response Class (Status 200)
Model | Model Schema

```

{
  "content": [
    {
      "code": "string",
      "name": "string"
    }
  ]
}

```

Response Content Type
application/json

Parameter	Value	Description	Parameter Type	Data Type
order	<input type="text"/>	Optional. Choose the field used to order the list (code or name)	query	string
limit	<input type="text"/>	Optional. Choose the max size of the list. If a limit count is given, no more than that many rows will be returned (but possibly less, if the query itself yields less rows)	query	integer
offset	<input type="text"/>	Optional. Choose to skip that many rows before beginning to return rows. OFFSET 0 is the same as omitting the OFFSET clause	query	integer

[Try it out!](#)

- b. Click the **Try it out!** button.
- c. Scroll down the page and find the **Response Body** section:

Request URL
`https://standartens.edqm.eu:443/standartens/api/v1/languages`

Response Body

```

{
  "content": [
    {
      "code": "sq",
      "name": "Albanian"
    },
    {
      "code": "bg",
      "name": "Bulgarian"
    },
    {
      "code": "zh",
      "name": "Chinese"
    },
    {
      "code": "hr",
      "name": "Croatian"
    },
    {
      "code": "cs",
      "name": "Czech"
    },
    {
      "code": "da",
      "name": "Danish"
    },
    {
      "code": "de",
      "name": "German"
    },
    {
      "code": "el",
      "name": "Greek"
    },
    {
      "code": "en",
      "name": "English"
    },
    {
      "code": "es",
      "name": "Spanish"
    },
    {
      "code": "fr",
      "name": "French"
    },
    {
      "code": "it",
      "name": "Italian"
    },
    {
      "code": "nl",
      "name": "Dutch"
    },
    {
      "code": "pl",
      "name": "Polish"
    },
    {
      "code": "pt",
      "name": "Portuguese"
    },
    {
      "code": "ro",
      "name": "Romanian"
    },
    {
      "code": "ru",
      "name": "Russian"
    },
    {
      "code": "sk",
      "name": "Slovak"
    },
    {
      "code": "sl",
      "name": "Slovenian"
    },
    {
      "code": "sv",
      "name": "Swedish"
    },
    {
      "code": "tr",
      "name": "Turkish"
    },
    {
      "code": "uk",
      "name": "Ukrainian"
    }
  ]
}

```

- d. Copy the content from **Response Body** and save it in a text file with the name `EDQM_Languages.json`.

- e. Scroll down the same page and expand the `/regions` API by clicking the associated link.

The screenshot shows the Swagger UI for the `GET /regions` endpoint. It includes the following sections:

- Implementation Notes:** Returns list of Region objects.
- Response Class (Status 200):** Model Schema showing a JSON structure:


```
{
  "content": [
    {
      "code": "string",
      "name": "string"
    }
  ]
}
```
- Response Content Type:** A dropdown menu set to `application/json`.
- Parameters:** A table with columns: Parameter, Value, Description, Parameter Type, and Data Type.

Parameter	Value	Description	Parameter Type	Data Type
order	<input type="text"/>	Optional. Choose the field used to order the list (code or name)	query	string
limit	<input type="text"/>	Optional. Choose the max size of the list. If a limit count is given, no more than that many rows will be returned (but possibly less, if the query itself yields less rows)	query	integer
offset	<input type="text"/>	Optional. Choose to skip that many rows before beginning to return rows. OFFSET 0 is the same as omitting the OFFSET clause	query	integer
- Try it out!** button.

- f. Click **Try it out!**
- g. Scroll down the page and find the **Response Body** section:

The screenshot shows the Swagger UI after clicking "Try it out!". It displays the following sections:

- Request URL:** `https://standards.edqm.eu:443/standards/api/v1/regions`
- Response Body:** A scrollable area containing the JSON response:


```
{
  "content": [
    {
      "code": "al",
      "name": "Albania"
    },
    {
      "code": "bg",
      "name": "Bulgaria"
    },
    {
      "code": "cn",
      "name": "China"
    },
    {
      "code": "hr",
      "name": "Croatia"
    },
    {
      "code": "de",
      "name": "Germany"
    }
  ]
}
```
- Response Code:** `200`

- h. Copy the content from **Response Body** and save it in a text file with the name `EDQM_Regions.json`.

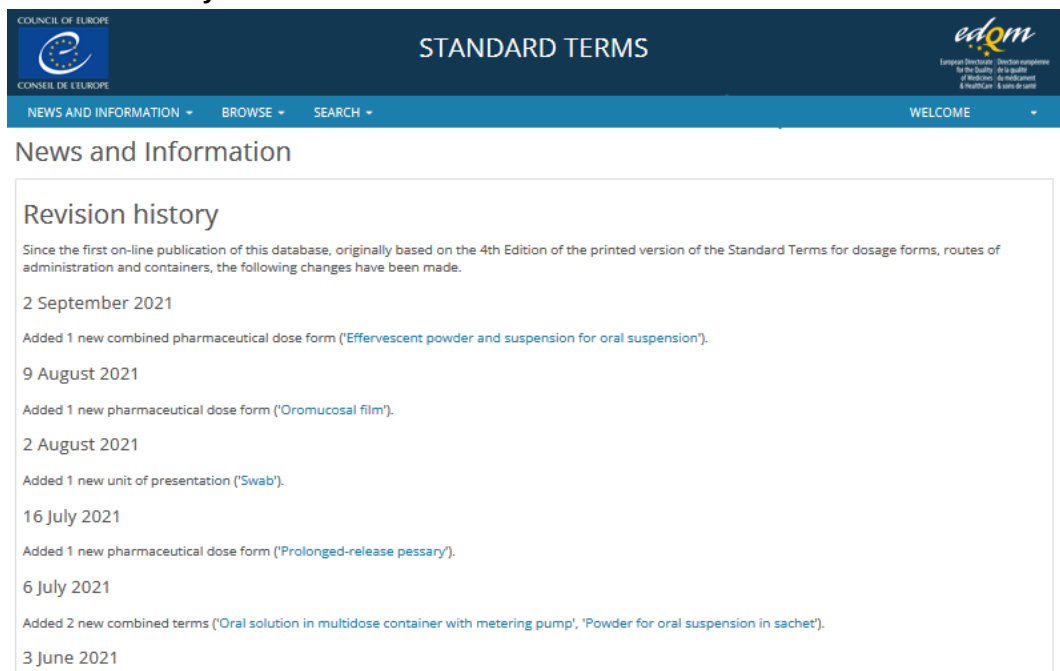
 **Note:**

Make sure the API call returns data without any error.

Check revisions for the EDQM standard terms database

The following steps describe how to check for any revisions published by EDQM since the last time your files were downloaded.

1. Access the [EDQM Standard Terms](#).
2. Log in using your credentials.
3. From the navigation menu options, choose **NEWS AND INFORMATION** and then **Revision History**.



The screenshot shows the EDQM Standard Terms website. The header includes the Council of Europe logo and the EDQM logo. The navigation menu has options for NEWS AND INFORMATION, BROWSE, SEARCH, and WELCOME. The main content area is titled "News and Information" and contains a "Revision history" section. The revision history text reads: "Since the first on-line publication of this database, originally based on the 4th Edition of the printed version of the Standard Terms for dosage forms, routes of administration and containers, the following changes have been made." The list of revisions includes: 2 September 2021 (Added 1 new combined pharmaceutical dose form), 9 August 2021 (Added 1 new pharmaceutical dose form), 2 August 2021 (Added 1 new unit of presentation), 16 July 2021 (Added 1 new pharmaceutical dose form), 6 July 2021 (Added 2 new combined terms), and 3 June 2021.

4. Check the revision date.
5. If there are any revisions published by EDQM since the last time the files were downloaded, plan to download the latest files and use the Dictionary Management EDQM utility to refresh the Argus database.

12

Set up a global administration account

1. Open **Argus Console** and go to **User Management**.
2. Select the user that needs access to **EDQM Dictionary Management**.
3. Use the **Select** button to add the **Global Admin** role and save the user configuration.
4. Make sure the **User Roles** section displays the **Global Admin** option:

The screenshot displays the 'Administrator' user configuration page in the Argus Console. The page is divided into several sections:

- User Name:** Administrator
- UserID:** admin
- Service User:**
- Application Access:** Argus, Insight, Console
- Default Application:** Argus
- Access:** Account Disabled, Security Disabled Account, Force Password Change At Login, Force Password To Expire Every [] Days
- Site:** []
- UserType:** ARGUS USER
- User Group:** Administrator Group
- User Roles:** AC Library Admin, Copy Configuration, **Global Admin** (highlighted with a red box), Enterprise User, Workflow Manager

13

Frequently asked questions

This chapter contains the most frequently asked questions about the EDQM setup:

- Does the EDQM solution provided by Argus allow you to configure an EDQM term ID?
- What will happen to our custom codelist after upgrade?
- Why is the new factory data added to codelist with the display attribute unchecked?
- Do I need to send EDQM terminology for Dose Form and Routes of Administration since there is a provision to send free-text?
- Does the EDQM term ID get copied when performing a copy action for a term?
- If a case in E2B(R3) format is submitted to EMA and then follow-up data which requires EDQM terminology processing is received, what needs to be done from the data entry perspective?
- Will there be any impact on any reports submitted prior to Argus release which include the EDQM RoA and DF solution?
- Will there be any impact on any reports such as E2B(R2), PMDA, eVAERS, eMDR?
- Does EDQM publish data file containing standard term list in the form of XLS or ZIP?
- Does EDQM provide delta updates for standard term database changes?
- When FDA, PMDA and other agencies go live with EDQM, will additional configurations be required?
- Why does the OOTB profile send codeSystemVersion for Route of Administration and Dose Formulation, even though these are optional?
- What happens if the same dictionary files are loaded again using the Dictionary Management utility, EDQM option?
- Is there a mandate date for MFSD when you use the EDQM terminology?
- What is the purpose of different hierarchies (like CDF, PDF, PFT and BDF) for Dose Formulation? Do we have any guidelines to use these terms?
- Does Argus establish connectivity with EDQM site/system?
- Is there any downtime required for the system during the Load process in Dictionary Management, EDQM option?
- What happens if a new term is added to EDQM Standard List?
- What happens if an existing term from the Argus codelist is deprecated or rejected by EDQM?
- What happens if a non-standard term, already present in the Argus codelist, is added to the EDQM Standard dictionary?
- What happens if the English text is revised by EDQM for a standard term?
- What will happen if EDQM removes a term from the Standard List?
- Where can you see the EDQM Term ID in the UI for Dose Form and Routes of Administration?

- Can you view EDQM terms pertaining to languages other than English or Japanese?

Does the EDQM solution provided by Argus allow you to configure an EDQM term ID?

No, it doesn't. According to ICH guidelines, terms should not be altered by the user. The administrator can load new terms into the system by using the **EDQM** option for **Dictionary Management** on the **Tools** tab of the menu bar and make the terms available for data entry.

What will happen to our custom codelist after upgrade?

Any custom values added by the user are retained with the existing attributes for **Display**. If new factory data added as part of Argus Release are the same as the ones with custom values, the user needs to take care of duplicate values in the codelist and do the required data migration.

Why is the new factory data added to codelist with the display attribute unchecked?

For new terms added through factory data, the **Display** attribute is set to **un-checked**. This is based on the feedback from users to avoid displaying additional terms to the end user as the decision to start using these new terms should be done at organization level and documented. These terms can be marked as **Display=Checked** in the Console application.

Do I need to send EDQM terminology for Dose Form and Routes of Administration since there is a provision to send free-text?

Yes you do. According to ICH guidelines, standard terms need to be sent for Dose Form and Route of Administration. You can include non-standard terms without the EDQM Term ID by submitting free-text and when it is intended only for specific uses such as adverse-event reporting.

Does the EDQM term ID get copied when performing a copy action for a term?

No, it doesn't. The Dose Formulation and Route of Administration term copy action does not copy the EDQM Term ID for copied terms.

If a case in E2B(R3) format is submitted to EMA and then follow-up data which requires EDQM terminology processing

is received, what needs to be done from the data entry perspective?

There is no need to modify any case data. Generating follow-up report will map the Dose Form and Route of Administration to appropriate EDQM Term ID and transmit required elements with EDQM terminology.

Will there be any impact on any reports submitted prior to Argus release which include the EDQM RoA and DF solution?

There is no impact on existing reports submitted prior to the release.

Will there be any impact on any reports such as E2B(R2), PMDA, eVAERS, eMDR?

No, there is no impact on these reports. These reports will retain their functionality to report corresponding codes for Dose Form and Route of Administration defined by respective agency.

Does EDQM publish data file containing standard term list in the form of XLS or ZIP?

No, it doesn't. Currently, the standard list can be accessed only via API which provides data in JSON format.

Does EDQM provide delta updates for standard term database changes?

Not yet. The EDQM website publishes **News and Information** with Revision history. The entire list is accessible as part of API response.

When FDA, PMDA and other agencies go live with EDQM, will additional configurations be required?

No separate configurations or data population are required for FDA, PMDA and other agency reporting. The respective E2B profiles can use the existing architecture to populate EDQM related data in ICSR reports.

Why does the OOTB profile send codeSystemVersion for Route of Administration and Dose Formulation, even though these are optional?

The `codeSystemVersion` elements are not required for Dose Form and Route of Administration, as these are optional. Argus populates these data to be consistent with `codeSystem` and `codeSystemVersion` implementation for HL7.

What happens if the same dictionary files are loaded again using the Dictionary Management utility, EDQM option?

The system will ensure that the data is in sync. There will not be any changes done to the Argus codelist.

Is there a mandate date for MFSD when you use the EDQM terminology?

As per MFSD regulation, the EDQM Term ID and Version elements are optional. Users can choose to send the EDQM Term ID and Version, or just free text in the G.k.4.r.9.1/ G.k.4.r.10.1/ G.k.4.r.11.1.

What is the purpose of different hierarchies (like CDF, PDF, PFT and BDF) for Dose Formulation? Do we have any guidelines to use these terms?

Each term is categorized into one or many concept classes by EDQM as follows:

- PDF - Pharmaceutical Dose Form
- CDF - Combined Pharmaceutical Dosage Form
- BDF - Basic Dose Form
- PFT - Patient Friendly Term

Each agency will determine the guideline to use these in case a term belongs to multiple concept classes. Factory data is provided to consider the priority in the order: **PDF, CDF, BDF, PFT**. Users can change this priority before loading new dictionary files.

Does Argus establish connectivity with EDQM site/system?

Not directly. Your Global administrator will need to connect to the EDQM website externally and extract the standard codelist files outside of Argus.

Is there any downtime required for the system during the Load process in Dictionary Management, EDQM option?

There is no downtime needed when the **Load** process is running. The EDQM updates will be effective only after the **Load** process is successfully completed.

What happens if a new term is added to EDQM Standard List?

If a new dictionary is loaded to Argus with new terms, it will add those terms to the respective Argus codelist but only if no other matching terms exist. The new terms will be marked as `Display=un-checked` and are not available for data entry. Global admin user can modify the `Display` attribute in Console to make it available for data entry.

What happens if an existing term from the Argus codelist is deprecated or rejected by EDQM?

If an active term is rejected or deprecated by EDQM, a new dictionary is loaded in Argus and the invalid term will be marked as `Display=un-checked` in Argus Code List.

This term will be visible in Argus Case form preceding a * symbol for existing cases, but it will not be available to be selected for entering data. The report will continue to display the correct term for the existing cases, where the terms are marked as `Display=unchecked`.

What happens if a non-standard term, already present in the Argus codelist, is added to the EDQM Standard dictionary?

If a new dictionary is loaded to Argus with the inclusion of a term, Argus will automatically link the existing Argus codelist term to its respective EDQM standard term. It will not add a duplicate term in Argus code list.

What happens if the English text is revised by EDQM for a standard term?

When a new dictionary is loaded to Argus with text changes, Argus will update the corresponding codelist term text with the revised text in the codelist. The revised text will be displayed for existing and new cases for that data entry. The user does not need to select the revised term.

What will happen if EDQM removes a term from the Standard List?

According to the EDQM documentation: [Introduction and guidance for use](#) (v.2.1.3, 16/11/18), the Standard Term database is incremental. Any **Standard Term** that is no longer approved

for use is not physically removed from the database and it is maintained in order to cover the legacy data with the status **Deprecated**.

Where can you see the EDQM Term ID in the UI for Dose Form and Routes of Administration?

The **EDQM Term ID** column is displayed in Argus Console, in the Code Lists tab, on the Argus Formulation and Routes of Administration screen.

Can you view EDQM terms pertaining to languages other than English or Japanese?

No, you can't. Currently, only EDQM terms for English can be viewed in the Formulation and Routes of Administration screen from Argus Console. Japanese terms can be viewed when EDQM extends its support for Japan.