



# **Ennov InSight IDMP 7.3**

## Contents

<b>Ennov InSight IDMP .....</b>	<b>1</b>
Generate IDMP Data.....	1
IDMP Data Generation Wizard Entities.....	2
Search Criteria Selection.....	2
IDMP Search Results Messages Examples.....	3
IDMP Data Validation.....	3
<b>IDMP Validation Messages.....</b>	<b>5</b>
IDMP Submission Info Messages Examples.....	6
IDMP Submission Warning Messages Examples.....	7
IDMP Submission Error Messages Examples.....	8
<b>IDMP Versioning.....</b>	<b>10</b>
<b>IDMP Data Visualization.....</b>	<b>14</b>
Configure IDMP Data Visualization.....	14
Use IDMP Data Visualization.....	15
IDMP Data Visualization Attributes for SPOR Values.....	16
Color Coding.....	17
Data Visualization Navigation Tree.....	18
<b>SPOR Integration.....</b>	<b>20</b>
Retrieving the RMS Data.....	22
Retrieving the OMS Data.....	22
<b>Index.....</b>	<b>24</b>

## Ennov InSight IDMP

Ennov InSight for IDMP introduces a standardized and structured method of collecting and evaluating authorized medicinal product data.

The Ennov InSight Identification of Medicinal Products (IDMP) module allows you to capture, maintain, and validate data about pharmaceutical products to comply with the European Medicine Agency (EMA) implementation of the International Organization for Standardization (ISO) standards for IDMP.

Use Ennov InSight IDMP module to:

- Add and update IDMP data
- Identify candidate data sets for submission
- Validate IDMP data for completeness and correctness
- Create and validate IDMP messages

With IDMP Data Generation wizard, you can:

- Generate a draft of medicinal product data in the FHIR format. FHIR is used for exchanging electronic health care data between systems for data analysis. Ennov InSight supports FHIR version 5.0.

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*Note: With this release, only POC is available for FHIR data generation. Full implementation will be available in future release.*

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- Use the medicinal product action for the data generation.
- Search for medicinal product actions using search criteria.

The validation errors and warnings with links to the related source data are displayed in **Job Requests**. See *IDMP Data Validation*.

The validation messages from **Job Requests** are also available on the IDMP Data Visualization page.

The IDMP Data Visualization structure displays color-coded icons to enable easy identification of nodes. See *Color Coding*.

## Generate IDMP Data

Use *IDMP Data Generation* wizard to generate medicinal product data in the Fast Healthcare Interoperability Resources (FHIR) format to validate IDMP data and to view IDMP data in Data Visualization.

### Prerequisites

The *IDMP Data Generation* wizard is available only for users with **Write** permissions for IDMP license, and **Read** permissions for RPT (Registration Planning and Tracking), Product Detail Management (PDM) and Medical Product Action, and Data Administration rights set to **Yes**.

You can access the *IDMP Data Generation* wizard from the **Wizards** menu or from **I Am Looking To > Create New > IDMP Data Generation**.

1. Select the **Wizards > IDMP Data Generation**.
2. Select the wizard flow.
3. Click **Next**.
4. Select or enter the search criteria and click **Next**.
5. On the *Medicinal Product Actions Search Results* page, select medicinal product actions.
6. Click **Next**.  
On the *Selection Confirmation* page, see the message about data generation for the medicinal product actions selected is displayed.
7. Click **Next**.
8. On the *IDMP Data Generation Wizard Completed* page, see the message IDMP Data was sent for Generation. Check Job Requests for further details.
9. Click **Go to > Job Requests** to see the IDMP Data Generation status.

### IDMP Data Generation Wizard Entities

Collect the IDMP data and validate it accordingly with Ennov InSight IDMP Data Generation wizard.

The wizard guides you through a series of well-defined steps. The Medicinal Product Actions entity is a route entity under which all the information from the Ennov InSight entities is collected.

Entity Name	Description
Initial Generation	Enables you to select medicinal product properties for generating data in Fast Healthcare Interoperability Resources (FHIR) format.

### Search Criteria Selection

Select the criteria for the search for future medicinal product data generation and validation.

The following criteria are available:

Section	Description
Action Name	Medicinal product action name.
Application Name	The name of the application.
Country	Application country.
Display Columns	Columns displayed in the search results.
Family Name	The name of the family.
Family Type	The type of the family.
Product Name	The name of the product.

Section	Description
Registration	Registrations based on the selected applications and product families.
Status	Medicinal product action status such as <b>In Draft</b> , <b>In Review</b> , <b>QCed</b> , <b>Submitted</b> . You should select at least one value to run <b>IDMP Data Generation</b> .
Sort Order	Order to display the results.

### IDMP Search Results Messages Examples

The detected errors and warnings that appear on the Medicinal Product Actions Search Results page.

Search Message Example	Description	Countries	Other Conditions and Results
Action Name [NAME] with Medicinal Product [NAME] for Registration Country [COUNTRY]. There are multiple Registrations assigned. In order to continue only one Registration should remain.	This message is displayed when there are multiple registrations for countries with single medicinal product.	Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, Germany, Ireland, Latvia, Luxembourg, Malta, Netherlands, Poland, Slovakia, Spain and Sweden and Iceland, Liechtenstein with Norway.	If there is one registration for one medicinal product, the <b>IDMP Data Generation</b> will be successfully completed. On the <i>Data Visualization</i> page, the <b>Marketing Authorisation</b> node will have one child node with a <b>License Code</b> name.

### IDMP Data Validation

Statuses of medicinal product data validation in Job Requests.

The following are the statuses for medicinal product data validation.

Section	Description
Failed	The reasons for validation failure are displayed under <b>Details</b> . The links for the Failed status navigate to the entity fields that must be fixed to pass the validation.
Completed	When the validation is successful, a draft file in Fast Healthcare Interoperability Resources (FHIR) format is generated in the appropriate Document Management System (DMS) location. Clicking the link downloads the file.

Section	Description
Completed with Warnings	To achieve successful validation, follow the information in the messages and resolve the issues described. The warnings' reasons are displayed under <b>Details</b> .

## IDMP Validation Messages

Validation messages related to IDMP data generation are displayed under Job Requests.

Validation messages may include information (info), errors and warnings.

Ennov InSight IDMP Data Generation wizard collects data and sends it to the data manager micro service for initial (raw) data conversion and validation. If the validation is successful, data is converted to Fast Healthcare Interoperability Resources (FHIR) format. The status of data generation is shown under **Job Requests**. Error, info and warning messages related to validation appear under **Job Requests**.

The validation messages from **Job Requests** are also available on the *IDMP Data Visualization* page.

See *IDMP Data Validation*, *IDMP Submission Info Messages Examples*, *IDMP Submission Warning Messages Examples* and *IDMP Submission Error Messages Examples*.

## IDMP Submission Info Messages Examples

The following table represents messages for successful validation after IDMP Data Generation wizard completion.

Job Name	Job Message Name	Job Message Example	Description
IDMP Data Generation Initial Flow	Info	Collecting Data to be sent to external system to generate IDMP submission.	This message is displayed in the IDMP Data Generation Initial Flow job details when data is collected for further processing and validation.
		Sending Data for External System for further processing.	This message is displayed in the IDMP Data Generation Initial Flow job details when data is prepared for processing in data manager.
		Data sent for External System for processing.	This message is displayed in the IDMP Data Generation Initial Flow job details when data is ready for processing.
		External System started processing the data.	This message is displayed in the IDMP Data Generation Initial Flow job details indicating the start of data processing.
		Job completed successfully. No errors found.	This message is displayed in the IDMP Data Generation Initial Flow job details indication the successful data validation.
		XML file can be downloaded following by the link: [medicinal product action name]- 138115.xml	This message is displayed in the IDMP Data Generation Initial Flow job details when the data is converted to Fast Healthcare Interoperability Resources (FHIR) format. XML file name is presented in the format: [Medicinal Product Action name]- Medicinal Product Action Identifier (medicinal product actions name ID from database).xml

## IDMP Submission Warning Messages Examples

The following table represents warnings that you might encounter after IDMP Data Generation wizard completion.

Job Name	Job Message Name	Job Message Example	Description
IDMP Data Generation Initial Flow	Warning	[Entity Type]: [Entity Name]: [Field Name] field has following warning: [Entity Name] should have SPOR value associated.	This message is displayed in the IDMP Data Generation Initial Flow job details if the required fields do not have SPOR value.
		[Entity Type]: [Entity Name]: [Field Name] field has following warning: Value is missing in the system.	This message is displayed in the IDMP Data Generation Initial Flow job details when the corresponding values for substance, active ingredients, registrations, CP applications, or medicinal products are absent.

## IDMP Submission Error Messages Examples

List of IDMP Data Generation errors and their meaning.

Job Name	Job Message Name	Job Message Example	Description
IDMP Data Generation Initial Flow	Error	[Entity Type]: [Entity Name]: [Field Name] field has following error: Required value is missing in the system.	This message is displayed in the IDMP Data Generation Initial Flow job details when the corresponding required field does not have data.
		[Entity Type]: [Entity Name]: [Field Name] field has following error: [FieldName] must have SPOR value associated.	This message is displayed in the IDMP Data Generation Initial Flow job details when the required field does not have SPOR value.
		[Entity Type]: [Entity Name]: [Field Name] field has following error: '[DA Entity Name]' must have SPOR value associated.	This message is displayed in the IDMP Data Generation Initial Flow job details when the required Data Administration entity does not have an associated SPOR value.
		[Entity Type]: [Entity Name]: [Field Name] field has following error: Value should be single not multiple for the attribute.	This message is displayed in the IDMP Data Generation Initial Flow job details when there is more than one value assigned to the field or entity.
		[Entity Type]: [Entity Name]: [Field Name] field has following error: Inconsistent or empty value for the repeatable entities.	This message is displayed in the IDMP Data Generation Initial Flow job details when different values are used for the entity field instead of one for consistency. For example, <b>Legal Basis</b> value must be equal for all the licences under medicinal product. Otherwise, the following message will be displayed: Application: Application name: Legal Basis field has following error: Inconsistent or empty value for the repeatable entities.
©Ennov 2024 Ennov		[Entity Type]: [Entity Name]: [Field Name] field has following error: SPOR	This message is displayed in the IDMP Data Generation Initial Flow job details when the required field does not have <b>Current or</b>

## IDMP Versioning

IDMP versioning helps tracking updates made to the IDMP related business entities.

*Note: Business entity is a general term for all tabs, wizards, and other functionality available to you in Ennov InSight entities.*

For now, IDMP versioning updates are visible only in the database. By default, the version includes a 0 value, but if, for example, you perform Create or Update operation in the Product entity, the version gains +1 value. If you perform such operation again, the version gains +1 value, too, that have to sum up to 2 and so on. However, not all operations with entities result in the version value update.

You should have at least **Write** privileges for RPT/PDM license to get access to IDMP versioning.

The table shows the list of entities used in IDMP versioning:

Entity Name	Business Entity Name	Operation Types Supported
Product Family	Product Family screens	Read/Update
Product	Product screens	Create/Read/Update
Component Active Ingredient	Component Active Ingredient screens	Create/Read/Update
Component Ref AI	Component Reference Active Ingredient screens	Create/Read/Update
Pharmaceutical Product	Pharmaceutical Product screens	Create/Read/Update
Pharmaceutical Product Active Ingredient	Pharmaceutical Product Active Ingredient screens	Create/Read/Update
Pharmaceutical Product Reference Active Ingredient	Pharmaceutical Product Reference Active Ingredient screens	Create/Read/Update
Pharmaceutical Product Substance	Pharmaceutical Product Substance	Create/Read/Update
Pharmaceutical Product Reference Substance	Pharmaceutical Product Reference Substance	Create/Read/Update
Manufacturing Item	Manufacturing Item	Create/Read/Update
Manufacturing Item Active Ingredient	Manufacturing Item Active Ingredient	Create/Read/Update

Entity Name	Business Entity Name	Operation Types Supported
Manufacturing Item Reference Active Ingredient	Manufacturing Item Reference Active Ingredient	Create/Read/Update
Manufacturing Item Substance	Manufacturing Item Substance	Create/Read/Update
Manufacturing Item Reference Substance	Manufacturing Item Reference Substance	Create/Read/Update
Application	<ul style="list-style-type: none"> <li>– Wizards:               <ol style="list-style-type: none"> <li>1. Create Application</li> <li>2. Update Application</li> </ol> </li> <li>– Tabs:               <ol style="list-style-type: none"> <li>1. Associate/Dissociate Products</li> <li>2. Add Application Country</li> </ol> </li> </ul>	Create/Read/Update
Orphan Designation	Orphan Designation	Create/Read/Update
Event	Event: <ul style="list-style-type: none"> <li>– Tabs:               <ol style="list-style-type: none"> <li>1. Associated/Dissociate Product</li> <li>2. Add Event Country</li> </ol> </li> </ul>	Create/Read/Update
PDS Indications/Intended Use Detail	Indications/Intended Use	Create/Read/Update
PDS Intended Effect/Comorbidity	Intended Effect/Comorbidity	Create/Read/Update
PDS Active Ingredient Detail	Active Ingredient	Read/Update
PDS Flue Strain Detail	Flue Strain	Create/Read/Update
PDS Species Details	Species	Create/Read/Update
PDS Medical Device Detail	Medical Device	Create/Read/Update
PDS Manufacturer Detail	Manufacturer	Create/Read/Update
PDS Packaging Detail	Packaging	Create/Read/Update

Entity Name	Business Entity Name	Operation Types Supported
PDS Package Set Detail	Package Set	Create/Read/Update
PDS Substance Detail	Substance	Create/Read/Update
PDS Shelf Life Detail	Shelf Life	Create/Read/Update
PDS Flu Strain Detail	Flu Strain	Create/Read/Update
PDS Pack Size Detail	Pack Size	Create/Read/Update
Registration	<ul style="list-style-type: none"> <li>– Registration</li> <li>– Associate Package Sets</li> </ul>	Create/Read/Update (for Registration)
Registration Package Set	<ul style="list-style-type: none"> <li>– Registration Package Set</li> <li>– Associate Country</li> </ul>	Read/Update (for Registration Package Set)
Registration Package Set Country	Registration Package Set Country	Create/Read/Update
Registration Package Description	Registration Package Description	Create/Read/Update
Medicinal Product	<ul style="list-style-type: none"> <li>– Medicinal Product</li> <li>– Associate/Dissociate Pharmaceutical Product</li> </ul>	Create/Read/Update (for Medicinal Product)
Product Cross-Reference	Product Cross-Reference	Create/Read/Update
Medicinal Product Names	Medicinal Product Names	Create/Read/Update
Medicinal Product Actions	Medicinal Product Actions	Create/Read/Update
Medicinal Product Attached Document	Medicinal Product Attached Document	Create/Read/Update
Data Administration: Manufactured Values > Manufacturer Global Detail	<ul style="list-style-type: none"> <li>– Manufactured Values</li> <li>– Global Product Details</li> <li>– Manufacturer Authorisation Reference Number</li> <li>– OMS</li> </ul>	Create/Update (for Manufactured Values)
Data Administration: Substance Values	<ul style="list-style-type: none"> <li>– Substance Values</li> <li>– SMS</li> </ul>	Create/Update (for Substance Values)

Entity Name	Business Entity Name	Operation Types Supported
Data Administration: Certificate Master File Values	Certified Master File Values	Create/Update

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***Note:** If the e-Signature that is added through the entity configuration is updated, the Version field value increases by 1.*

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## IDMP Data Visualization

Data Visualization (DV) provides visual display of data to easily understand complex data.

You need at least **Read** permissions for Product Detail Management (PDM), Registration Planning and Tracking (RPT), permissions for **Medicinal Product Action** entity security, and **Write** permissions for **IDMP** license to enable data visualization for medicinal product action.

In Ennov InSight , Data Visualization (DV) provides graphical representation of information and data. The visualization is informative, and enables you to analyze data for making the required decisions. Data Visualization also marks entity fields with a symbol denoting an error or a warning when data fails to meet validation criteria. The **DV** option will be available after data is generated using **IDMP Data Generation** wizard at least one time.

Using the **DV** option on the *Medicinal Product Actions Attributes* page, you can:

- Display the data structure within the hierarchical information. The top-level nodes introduce medicinal product name, each subsequent level indicates specific product categories or individual attributes. The color of the nodes within the tree map can be used to indicate additional data. See *Ennov InSight for IDMP > IDMP Data Visualization > Color Coding*.
  - Filter, search, and navigate through the entities within the tree.
- View data with IDMP schema color-coding. It can be switched on or off using configuration. See *Configure IDMP Data Visualization Module*.

### Data Visualization Validation

All validation messages that are displayed in Job Request are mirrored in Data Visualization.

## Configure IDMP Data Visualization

IDMP color-coding and other parameters can be configured for visual display of data.

### Prerequisites



*Warning: The steps below can be performed by Technical Consulting Team only. Contact your Business Development Representative for assistance to configure IDMP Data Visualization module.*

To configure the data visualization:

1. Verify that `ai.calyx.ui.widget.enable` parameter is set to true in `insight.var` file.
2. Locate the `widget.config.json` file in `<Drive>: \InSightManager\server\all\conf\insight` folder.
3. Verify the following main parameters:

Parameter	Description
"colorScheme"	colorScheme is used to enable or disable visual display of data. Setting colorScheme to <code>true</code> displays hierarchy tree and attributes in color. If colorScheme is set to <code>false</code> , the hierarchy tree and attributes will be displayed without color-coding. By default, this parameter is <code>true</code> .
"language"	The language in which the labels are displayed. By default, the language is English.
"minCharCount"	The minimum character required in the search and filter fields for the operation to process. By default, the minCharCount is 5. If "minCharCount" is changed, the search or filtering happens only after the specified number of characters are entered in the search field. If less number of characters are entered, a warning message will displayed.
"splitter"	Component used for rendering visual data. The following are the default values for splitter. <pre>"splitter": {"left": {"min": "30%", "size": "30%"}, "right": {"min": "35%"}</pre>

4. Change the parameter values as required.
5. Save changes.

## Use IDMP Data Visualization

Use Data Visualization (DV) to view complex data in visual and graphical representation.

### Prerequisites

Data must be generated using **IDMP Data Generation** wizard for the medicinal product action to activate the **DV** icon on the *Medicinal Product Action Attributes* page. See *Generate IDMP Data*.

To use data visualization:

1. Go to **Application Attributes > Medicinal Product Actions** tab, select the required medicinal product action.
2. On the *Medicinal Product Action Attributes* page, click **DV**.  
The *IDMP Data Visualization* page appears. The IDMP Data is displayed with IDMP schema specified color-coding on the associated classes and sub-classes.
3. Modify the required data from the entity pages or navigate to the entity from a message in *Job Requests*.
4. Select the **Wizards > IDMP Data Generation**.
5. Select the wizard flow.
6. Click **Next**.

7. Select or enter the search criteria and click **Next**.
8. On the *Medicinal Product Actions Search Results* page, select the medicinal product actions.
9. Click **Next**.  
On the *Selection Confirmation* page, see the message about data generation for the medicinal product actions selected is displayed.
10. Click **Next**.
11. On the *IDMP Data Generation Wizard Completed* page, see the message IDMP Data was sent for generation. Check Job Requests for further details.
12. Click **Finish**.
13. To see the IDMP Data Generation status, click **Go to > Job Requests**.
14. After the IDMP Data Generation is complete, go back to **Medicinal Product Action** tab, select the required medicinal product action.
15. On the *Medicinal Product Action Attributes* page, click **DV**.  
The modified information is displayed on IDMP Data Visualization.
16. Click the cross icon to close the *IDMP Data Visualization* page.  
The *Medicinal Product Action Attributes* page is displayed.

## IDMP Data Visualization Attributes for SPOR Values

The names of the nodes used to indicate additional data and represent specific attributes or meanings and their display rules.

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***Note:** If an entity selected does not have SPOR values associated in Data Administration, there will be no values for this entity field on the Data Visualization page. Select the icon next to the field to view the information.*

*For example, to display the values for the Orphan Designation Status field on the Data Visualization page, associate the term from the RMS tab in Data Administration > Orphan Status Values.*

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All the SPOR values are displayed in the following format: <Term Name>/<RMS Term ID>/<Status>.

All the OMS values are taken from **Data Administration > SPOR Master Lists > Organization**. For example, to display the values for the **Marketing Authorisation Holder (Organisation)** field on the *Data Visualization* page, associate the term from the OMS tab in **Data Administration > MAH/Development Sponsor/ Organisation Values**.

The following is the Data Visualization hierarchical structure:

Medicinal Product

- PMSID, Medicinal Product Name
- Marketing Authorization

- Manufacturer/Business Operation
  - Operation Type, Manufacturer, Active Ingredient
- Therapeutic Indications
  - Indication, Intended Effect
- Medicinal Product
  - Marketing Authorisation Number, Pack Size
- Manufactured Item
  - Manufactured Dose Form, List (Active Ingredient + Strength)
- Certificate Master File
  - File Identifier Type : File Identifier, Substance Name
- Pharmaceutical Product
  - Administrable Dose Form, List (Active Ingredient + Strength)

## Color Coding


Data Visualization uses color coding to organize and categorize information using different colors.

Color Coding can be switched ON or OFF using configuration. See *Configure IDMP Data Visualization*.

The following table includes the colors of the nodes used to indicate additional data and represent specific attributes or meanings.

The top-level node indicates medicinal product name, each subsequent level indicates specific product categories or individual attributes. See the IDMP Class and the IDMP Sub Class columns below.

**Table 1: Parent Nodes**

Node Color	IDMP Class
	Medicinal Product Provenance Product Classification Orphan Designation Medicinal Product Name Product Cross Reference Attached Document Certificate Master File








Node Color	IDMP Class
	Marketing Authorization Marketing Authorization Number Marketing Authorization Procedure Regulatory Application
	Manufacturer/Business Operation
	Full Indication Therapeutic Indications
	Packaged Medicinal Product Manufactured Item Certificate Master File
	Pharmaceutical Product

Table 2: Child Nodes

Node Color	IDMP Sub Class
	Active Ingredient and Substances
	Marketing Authorization Holder Medicines Regulatory Agency (Organization)

## Data Visualization Navigation Tree

Navigation tree provides an easy way to view and access the specific information in the system.

Use the *IDMP Data Visualization* navigation tree to access the data of Ennov InSight entities generated for IDMP.

The *IDMP Data Visualization* page has one display mode and displays entities in the tree in hierarchical and convenient view with color-coding. The navigation tree consists of nodes with dependent sub-nodes.

Tree view shows the tree with the data set up related to the specific submission. This set of data may vary depending on the user data setup for IDMP.

The Medicinal Product Actions entity is a route entity under which all the information from other Ennov InSight entities is collected.

The **Filter Criteria** and **Search Option** enables you to see entities in the tree that contain the filter criteria entered.

In the tree view, the hierarchical display represents the relationship type. The terms parent, child, and sibling are used to specify the relationship types.

- Parent indicates a higher-level node or attribute that has related subnodes.
- Child nodes appear below and slightly to the right of the parent node indicating a relationship.
- Sibling nodes are equal in ranking, sharing a parent node.
- A child node can be a parent node for related subnodes.

You can click the arrow next to any node to expand or collapse areas of the navigation tree. Click any node in the tree to view the attributes page for the entity represented by the selected node. The details appear in the pane to the right of the navigation tree.

You can expand or collapse a root node by clicking right mouse button on the needed entity and select **Expand All** or **Collapse All**.

## SPOR Integration

To support the integration with EMA OMS and RMS API, and to enable adding the controlled vocabulary for organisations and referentials data from the external system, Ennov InSight provides the ability to enable and configure the SPOR services.

To start receiving data from the EMA SPOR REST Server, the options described in both the Configuration and Authentication sections must be set in the `insightConfig.bat` or `insight.var` file.

### Configuration

The SPOR services can be enabled and configured through the appropriate options in the `insightConfig.bat` or `insight.var` files:

**Table 3:** `insightConfig.bat`

<p>Under the <code>SPOR API Settings</code> section, values for the <code>Enable SPOR API RMS</code>, <code>Enable SPOR API OMS</code> and <code>Defined Interval (minutes)</code> options must be set.</p>	<p>By default, the <code>Enable SPOR API RMS</code> and <code>Enable SPOR API OMS</code> options are set to <code>false</code> and the <code>Defined Interval (minutes)</code> option is not populated with a value:</p> <ul style="list-style-type: none"> <li>– <code>Enable SPOR API for RMS: false</code></li> <li>– <code>Enable SPOR API for OMS: false</code></li> <li>– <code>Defined Interval (minutes):</code></li> </ul> <p>If you set the <code>Enable SPOR API for RMS</code> option to <code>true</code>, then the RMS data will be retrieved according to the rules described in the <i>Retrieving the RMS Data</i> topic.</p> <p>If you set the <code>Enable SPOR API for OMS</code> option to <code>true</code>, then the OMS data will be retrieved according to the rules described in the <i>Retrieving the OMS Data</i> topic.</p>
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**Table 4:** insight.var

<p>Under the SPOR API SETTINGS section, values for the <code>spor.api.enable.rms</code>, <code>spor.api.enable.oms</code> and <code>spor.api.update.interval.minutes</code> options must be set.</p>	<p>By default, the <code>spor.api.enable.rms</code>, <code>spor.api.enable.oms</code>, and the <code>spor.api.update.interval.minutes</code> option are not populated with a value:</p> <ul style="list-style-type: none"> <li>– <code>spor.api.enable.rms=</code></li> <li>– <code>spor.api.enable.oms=</code></li> <li>– <code>spor.api.update.interval.minutes=</code></li> </ul> <p>The acceptable values for the <code>spor.api.enable.rms</code> and <code>spor.api.enable.oms</code> are <code>true</code> or <code>false</code>.</p> <p>If you set the <code>spor.api.enable.rms</code> option to <code>true</code>, then the RMS data will be retrieved according to the rules described in the <i>Retrieving the RMS Data</i> topic.</p> <p>If you set the <code>spor.api.enable.oms</code> option to <code>true</code>, then the OMS data will be retrieved according to the rules described in the <i>Retrieving the RMS Data</i> topic.</p>
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## Authentication

To enable the authentication between the Ennov InSight system and the SPOR API client, Ennov InSight provides the ability to configure the authentication mechanism through the appropriate options in the `insightConfig.bat` or `insight.var` files:

**Table 5:** insightConfig.bat

<p>Under the SPOR API Settings section, values for the <code>User Name</code> and <code>Password</code> options must be set.</p>	<p>By default, both options appear blank:</p> <ul style="list-style-type: none"> <li>– <code>User Name:</code></li> <li>– <code>Password:</code></li> </ul>
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**Table 6:** insight.var

<p>Under the SPOR API SETTINGS section, values for the <code>spor.api.user</code> and <code>spor.api.password</code> options must be set.</p>	<p>By default, both options appear blank:</p> <ul style="list-style-type: none"> <li>– <code>spor.api.user=</code></li> <li>– <code>spor.api.password=</code></li> </ul>
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## Retrieving the RMS Data

The uniqueness of the values in any SPOR-related tables in the **Data Administration > SPOR Maintenance** section is defined by the concatenation of **Term Name** and **Term Identifier** values. This concatenation must be unique within SPOR RMS list.

When the configurations are completed in the `insightConfig.bat` or `insight.var` files, the values from the EMA SPOR REST Server are loaded to the corresponding tables in the Ennov InSight **Data Administration > SPOR Maintenance** section:

- ATC RMS Values
- Compendial Designation/Source RMS Values
- Concentration Measure Type RMS Values
- Country RMS Values
- Denominator/Numerator Unit RMS Values
- Dosage/Pharmaceutical Form RMS Values
- EMA Authorisation Status RMS Values
- Language RMS Values
- Legal Basis RMS Values
- Medical Device RMS Values
- Medicinal Product Type RMS Values
- Procedure Type RMS Values
- Route of Administration RMS Values
- Unit of Measure Prefix RMS Values

All values loaded from the EMA SPOR REST Server will have the status **Inactive** in Ennov InSight .

If you manually modify any loaded value, during the next loading the values are overwritten with the values from EMA SPOR REST Server.

The first loading starts in 5 minutes after all required settings are saved. The further loadings start according to the time value defined in the **Defined Interval (minutes)** attribute.

**Important:** If the started sync is not finished, but according to the set time interval the next one should be started, then it is not going to start until the previous is finished.

## Retrieving the OMS Data

### Important Information

In the Ennov InSight system the uniqueness of the MAH/Development Sponsor/Organisation information is determined by the **EV Code** value (**MAH/Development Sponsor/Organisation Values > MAH/Development Sponsor XEVMPD Information**), whilst in the EMA SPOR system it is determined by the **Organisation**

**Identifier** value. During the synchronisation, the matching EV Code value determines the MAH/Development Sponsor/Organisation information to be added to the Ennov InSight Data Administration table. If there are more matching EV Codes in the EMA SPOR system, then the first matching information found is synchronized. The other matching entries will be listed in the **Comments** field in a comma delimited manner.

It is recommended to set the `enable.spor.api.oms` option in the `insight.var` file, or the **Enable SPOR API for OMS** option in the `insightConfig.bat` file, to `true` only if there are no **MAH/Development Sponsor/Organisation Values** in the Ennov InSight system. If many **MAH/Development Sponsor/Organisation Values** entries exist, it is recommended to not retrieve data from the EMA SPOR system in order to eliminate the unnecessary structural data discrepancies.

When the configurations are completed in the `insightConfig.bat` or `insight.var` files, the values from the EMA SPOR REST Server are loaded to the corresponding tables in the Ennov InSight **Data Administration > Other** section:

— MAH/Development Sponsor/Organisation Values

The fields are populated according to their availability on the EMA SPOR REST Server. The **MAH/Development Sponsor XEVMPD Information** tab is populated for the values that are loaded from the EMA SPOR REST Server if the needed data exists in the SPOR API system. If set to `Active`, the loaded values from the **MAH/Development Sponsor/Organisation Values** table can be selected for Product Family and/or Registration (becomes available for selection only if the **MAH Code**, or **Sponsor Code** is populated).

All values loaded from the EMA SPOR REST Server will have the status **Inactive** in Ennov InSight .

If you manually modify any loaded value, during the next loading the values are overwritten with the values from EMA SPOR REST Server.

The first loading starts in 5 minutes after all required settings are saved. The further loadings start according to the time value defined in the **Defined Interval (minutes)** attribute.

# Index

## I

IDMP 1–3, 8

IDMP Data Visualization 14, 15

## N

Navigation 18

## P

Publishing 5–7

## R

Registrations 16, 17

## S

SPOR 20, 22