

## Choose Datasets step

### Datasets upload

- .xpt datasets can be uploaded either by dragging and dropping them or by clicking browse button
- If no dataset is uploaded, clicking on next button will return an error, saying that at least 1 .xpt file needs to be uploaded
- The maximum total size of .xpt files is 1 Gb, the maximum number of files is 50 items. If one of the limits is reached, a corresponding error occurs

#### Validation

1 Choose Datasets — 2 Choose Rules — 3 Validate — 4 View Report

##### Choose Datasets



Drag and drop, or [browse](#) your files

[Browse Define.xml](#)

[Next >](#)

## Choose Datasets step

### Define file upload

- .xml define files can be uploaded either by clicking “Browse Define .xml” browse button
- Define file upload is optional
- The maximum size is 5 Mb. If the limit is reached, an error occurs

#### Validation

1 Choose Datasets — 2 Choose Rules — 3 Validate — 4 View Report

##### Choose Datasets



Drag and drop, or [browse](#) your files

[Browse Define.xml](#)

[Next >](#)

## Choose datasets step

### Next button

- After all necessary files are uploaded, next button can be used

### Validation

1 Choose Datasets — 2 Choose Rules — 3 Validate — 4 View Report

#### Choose Datasets

File Name	Dataset Domain	Path	Files: 3
ae.xpt	N/A	D:\EPM_CLNS\demo data\demo data\happy\datasets\ae.xpt	×
cm.xpt	N/A	D:\EPM_CLNS\demo data\demo data\happy\datasets\cm.xpt	×
dm.xpt	N/A	D:\EPM_CLNS\demo data\demo data\happy\datasets\dm.xpt	×
Add Files			Remove All

Browse Define.xml

D:\EPM\_CLNS\demo data\demo data\happy\define-files\define.xml

Next >

## Choose Rules step

### CDISC Rules parameters

- These fields are for choosing the data model, its version and version of CT (Controlled Terminology)
- Data model and its version are preselected as currently this is the only version supported by CDISC Engine
- There is only one CDISC CT version available in the app as only 1 version was properly tested by our team. So, it is preselected as well. Generally, CDISC has 30+ CT versions.

#### Validation

✓ Choose Datasets — 2 Choose Rules — 3 Validate — 4 View Report

##### Choose Rules

▼ CDISC Rules

Data Model

SDTM

Model IG Version

3.4

CDISC CT

SDTM CT 2021-06-25

Add to List

> Custom Rules

> Regulatory Rules

> Sets of Rules


Type to search

CDISC Rules (0)

Custom Rules (0)

Regulatory Rules (0)

Sets Of Rules (0)



No Rules Yet

Please choose rules

Total Rules 0 Total Selected Rules 0

[< Back](#)[Choose Dictionaries](#)[Validate](#)

# Choose Rules step

## Add to list button

- In order to see CDISC Rules list “Add to List” button needs to be clicked

### Validation



Choose Rules

CDISC Rules

Data Model

SDTM

Model IG Version

3.4

CDISC CT

SDTM CT 2021-06-25

Add to List

Custom Rules

Regulatory Rules

Sets of Rules

Type to search

CDISC Rules (0)

Custom Rules (0)

Regulatory Rules (0)

Sets Of Rules (0)

No Rules Yet

Please choose rules

Total Rules 0

Total Selected Rules 0

Back

Choose Dictionaries

Validate

# Choose Rules step

## Managing CDISC Rules list

- All rules appears preselected
- They can be unchecked manually one by one or all at once

### Validation

✓ Choose Datasets — 2 Choose Rules — 3 Validate — 4 View Report

#### Choose Rules

CDISC Rules

Data Model  
SDTM

Model IG Version  
3.4

CDISC CT  
SDTM CT 2021-06-25

Add to List

Custom Rules

Regulatory Rules

Sets of Rules

Type to search

CDISC Rules (241) Custom Rules (0) Regulatory Rules (0) Sets Of Rules (0)

Rule ID	Description	Rule Severity
<input checked="" type="checkbox"/> CDISC.SDTMIG.CG0007	Raise an error when the date portion of --DTC is an incomplete date and the date portion of DM.RFSTDTC is an incomplete date, but --DY is not empty	Error
<input type="checkbox"/> CDISC.SDTMIG.CG0008	Raise an error when --TPTRF is empty, but --ELTM is not empty	Error
<input checked="" type="checkbox"/> CDISC.SDTMIG.CG0009	Raise an error when EPOCH is not in TA.EPOCH	Error
<input type="checkbox"/> CDISC.SDTMIG.CG0026	Trigger error when --TPTRF = null and --RFTDTC is populated	Error
<input checked="" type="checkbox"/> CDISC.SDTMIG.CG0029	Trigger error when domain is not an AP-- domain and USUBJID is not present in DM.USUBJID	Error

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Total Rules 241 Total Selected Rules 239

[< Back](#)[Choose Dictionaries](#)[Validate](#)

# Choose Rules step

## Managing CDISC Rules list

- Rules can be sorted by Rule ID, Description or Severity

### Validation

1 Choose Datasets 2 Choose Rules 3 Validate 4 View Report

CDISC Rules

Data Model

SDTM

Model IG Version

3.4

CDISC CT

SDTM CT 2021-06-25

Add to List

Custom Rules

Regulatory Rules

Sets of Rules

Type to search

CDISC Rules (241)

Custom Rules (0)

Regulatory Rules (0)

Sets Of Rules (0)

Rule ID ↑	Description	Rule Severity
<input checked="" type="checkbox"/> CDISC.SDTMIG.CG0007	Raise an error when the date portion of --DTC is an incomplete date and the date portion of DM.RFSTDTC is an incomplete date, but --DY is not empty	Error
<input type="checkbox"/> CDISC.SDTMIG.CG0008	Raise an error when --TPTREF is empty, but --ELTM is not empty	Error
<input checked="" type="checkbox"/> CDISC.SDTMIG.CG0009	Raise an error when EPOCH is not in TA.EPOCH	Error
<input type="checkbox"/> CDISC.SDTMIG.CG0026	Trigger error when --TPTREF = null and --RFTDTC is populated	Error
<input checked="" type="checkbox"/> CDISC.SDTMIG.CG0029	Trigger error when domain is not an AP-- domain and USUBJID is not present in DM.USUBJID	Error
<input checked="" type="checkbox"/> CDISC.SDTMIG.CG0031	Verify when VISIT is not null in any given domain and VISIT is planned (SVPRESP = 'Y'), then VISIT should be among TV.VISIT.	Error
<input checked="" type="checkbox"/> CDISC.SDTMIG.CG0032	Verify that visdty is planned and exists in TV	Error
<input checked="" type="checkbox"/> CDISC.SDTMIG.CG0033	Verify when VISITNUM is not null in any given domain and VISITNUM is planned (SVPRESP = 'Y'), then VISIT should be among TV.VISITNUM.	Error
<input checked="" type="checkbox"/> CDISC.SDTMIG.CG0034	If VISITNUM is not null then VISITNUM should be among SV.VISITNUM	Error
<input checked="" type="checkbox"/> CDISC.SDTMIG.CG0040	Raise an error when AEOCCUR exists in AE dataset.	Error
<input checked="" type="checkbox"/> CDISC.SDTMIG.CG0041	Raise an error when AESCAN, AESCONG, AESDISAB, AESDTH, AESHOSP, AESLIFE, AESOD or AESMIE = 'Y' and AESER = 'N' or is empty.	Error

Rows per page: 25

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Total Rules 241

Total Selected Rules 239

# Choose Rules step

## Managing CDISC Rules list

- Search can be applied either to all records or within specific category. Specific category can be chosen from the list or can be written manually

**Validation**

Choose Datasets | Choose Rules | Validate

**Choose Rules**

CDISC Rules

Data Model: SDTM

Model ID Version: 3.4

CDISC CT: SDTM CT 2021-06-25

Add to List

Search:

Rule ID:

Description:

Rule Severity:

CDISC.SDTMIG.CG0008 Raise an error when -TPTREF is empty, but -ELTM is n

CDISC.SDTMIG.CG0009 Raise an error when EPOCH is not in TA.EPOCH

CDISC.SDTMIG.CG0026 Trigger error when -TPTREF = null and -RFTDTC is pop

Search: 007

CDISC Rules (4) Custom Rules (0) Regulatory Rules (0) Sets Of Rules (0)

Rule ID	Description	Rule Severity
CDISC.SDTMIG.CG0007	Raise an error when the date portion of -DTC is an incomplete date and the date portion of DM.RFSTDTC is an incomplete date, but -DY is not empty	Error
CDISC.SDTMIG.CG0075	Raise an error when DVSTDTC is earlier than RFICDTC in DM.	Error
CDISC.SDTMIG.CG0078	Raise an issue if MHENDTC has a non-empty date that is on or after DM.RFSTDTC	Warning
CDISC.SDTMIG.CG0079	Raise an issue if MHSTDTC has a non-empty date that later than DM.RFSTDTC	Warning

Search: Rule Severity: warn

CDISC Rules (48) Custom Rules (0) Regulatory Rules (0) Sets Of Rules (0)

Rule ID	Description	Rule Severity
CDISC.SDTMIG.CG0027	Trigger error when -SCAT is not null and -SCAT is equal to -CAT	Warning
CDISC.SDTMIG.CG0035	Trigger error when VISITNUM is present in TV.VISITNUM and does not have a one-to-one relationship with VISIT	Warning
CDISC.SDTMIG.CG0042	Select record where AESCAN and AESCONG and AESDTH and AESHOSP and AESLIFE and AESOD and AESMIE ^= "Y" However, AESER ^= "N"	Warning
CDISC.SDTMIG.CG0049	Trigger error when -DECOD and -PTCD do not have a one-to-one relationship	Warning



# Choose Rules step

## Adding dictionaries

- “Add dictionary” button allows to add dictionaries that should be used during the validation
- Uploaded dictionaries will be “remembered” by the system for further usage

**Validation**

1 Choose Datasets 2 **Choose Rules** 3 Validate 4 View Report

**Choose Rules**

CDISC Rules

Data Model  
SDTM

Model ID Version  
3.4

CDISC CT  
SDTM CT 2021-06-25

Add to List

Custom Rules

Regulatory Rules

Sets of Rules

Search: Type to search

CDISC Rules (241) Custom Rules (0) Regulatory Rules (0) Sets Of Rules (0)

Rule ID	Description	Rule Severity
CDISC.SDTMIG.CG0007	Raise an error when the date portion of -DTC is an incomplete date and the date portion of DM.RFSTDTCT is an incomplete date, but -DY is not empty	Error
CDISC.SDTMIG.CG0008	Raise an error when -TPTREF is empty, but -ELTM is not empty	Error
CDISC.SDTMIG.CG0009	Raise an error when EPOCH is not in TA.EPOCH	Error
CDISC.SDTMIG.CG0026	Trigger error when -TPTREF = null and -RFTDTC is populated	Error
CDISC.SDTMIG.CG0029	Trigger error when domain is not an AP- domain and USUBJID is not present in DM.USUBJID	Error
CDISC.SDTMIG.CG0031	Verify when VISIT is not null in any given domain and VISIT is planned (SVPRESP = 'Y'), then VISIT should be among TV.VISIT.	Error
CDISC.SDTMIG.CG0032	Verify that visit is planned and exists in TV	Error
CDISC.SDTMIG.CG0033	Verify when VISITNUM is not null in any given domain and VISITNUM is planned (SVPRESP = 'Y'), then VISIT should be among TV.VISITNUM.	Error
CDISC.SDTMIG.CG0034	If VISITNUM is not null then VISITNUM should be among SV.VISITNUM	Error
CDISC.SDTMIG.CG0040	Raise an error when AEOCCUR exists in AE dataset.	Error
CDISC.SDTMIG.CG0041	Raise an error when AESCAN, AESCONG, AESDISAB, AESDTH, AESHOSP, AESLIFE, AESOD or AESMIE = 'Y' and AESER = 'N' or is empty.	Error

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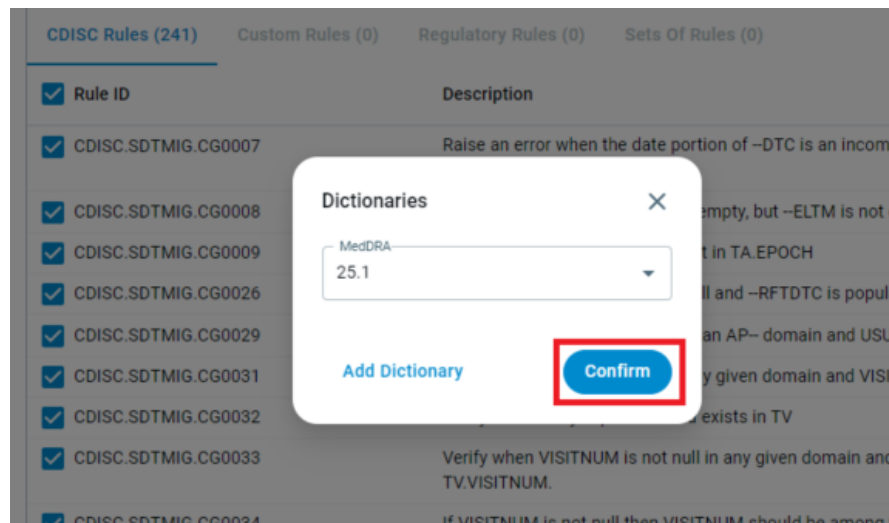
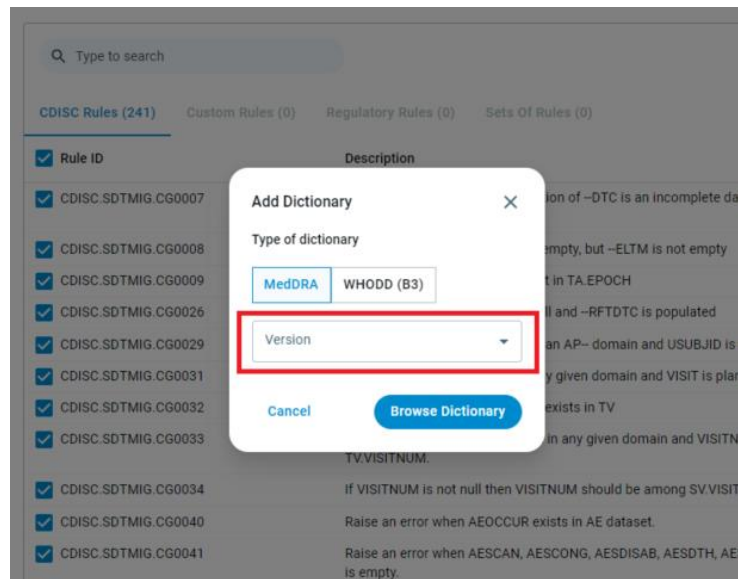
Total Rules 241 Total Selected Rules 241

< Back Add Dictionary Validate

## Choose Rules step

### Adding dictionaries

- Once dictionary type and its version is chosen, the dictionary can be browsed
- After dictionary is installed, a system notification about successful installation appears, and a modal window appears with the newly installed version of the dictionary preselected.
- Clicking on "Confirm" means that the selected dictionaries will be used during the validation (currently they will not, as dictionary related rules are not supported by CDISC yet)



# Validate step

## Validate button and validation process

- If at least one rule is selected “Validate” button can be used
- Dictionary related rules are currently not supported by CDISC
- Define file related rules are currently not supported by CDISC

Validation

Choose Datasets Choose Rules Validate View Report

Choose Rules

CDISC Rules (241) Custom Rules (0) Regulatory Rules (0) Sets of Rules (0)

Rule ID Description Rule Severity

<input checked="" type="checkbox"/> CDISC.SDTMG.C00007	Raise an error when the date portion of -DTC is an incomplete date and the date portion of DM.RFSTOTC is an incomplete date, but -DY is not empty	Error
<input type="checkbox"/> CDISC.SDTMG.C00008	Raise an error when -TPTREF is empty, but -ELTM is not empty	Error
<input checked="" type="checkbox"/> CDISC.SDTMG.C00009	Raise an error when EPOCH is not in TA.EPOCH	Error
<input type="checkbox"/> CDISC.SDTMG.C00026	Trigger error when -TPTREF = null and -RFSTOTC is populated	Error
<input checked="" type="checkbox"/> CDISC.SDTMG.C00029	Trigger error when domain is not an AP-domain and USUBJID is not present in DM.USUBJID	Error
<input checked="" type="checkbox"/> CDISC.SDTMG.C00031	Verify when VISIT is not null in any given domain and VISIT is planned (SV.PRESP = 'Y'), then VISIT should be among TV.VISIT	Error
<input checked="" type="checkbox"/> CDISC.SDTMG.C00032	Verify that visit is planned and exists in TV	Error
<input checked="" type="checkbox"/> CDISC.SDTMG.C00033	Verify when VISITNUM is not null in any given domain and VISITNUM is planned (SV.PRESP = 'Y'), then VISIT should be among TV.VISITNUM	Error
<input checked="" type="checkbox"/> CDISC.SDTMG.C00034	If VISITNUM is not null then VISITNUM should be among SV.VISITNUM	Error
<input checked="" type="checkbox"/> CDISC.SDTMG.C00040	Raise an error when AEDCCUR exists in AE dataset.	Error
<input checked="" type="checkbox"/> CDISC.SDTMG.C00041	Raise an error when AESCAN, AESCONG, AESDISAB, AESDTH, AESHOSR, AESLIFE, AESOD or AESME = 'Y' and AESER = 'N' or is empty	Error

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Total Rules 241 Total Selected Rules 239

Choose Dictionaries

Validate

Validation

Choose Datasets Choose Rules Validate View Report

Choose Rules

CDISC Rules (241) Custom Rules (0) Regulatory Rules (0) Sets of Rules (0)

Rule ID Description Rule Severity

<input checked="" type="checkbox"/> CDISC.SDTMG.C00007	Raise an error when the date portion of -DTC is an incomplete date and the date portion of DM.RFSTOTC is an incomplete date, but -DY is not empty	Error
<input type="checkbox"/> CDISC.SDTMG.C00008	Raise an error when -TPTREF is empty, but -ELTM is not empty	Error
<input checked="" type="checkbox"/> CDISC.SDTMG.C00009	Raise an error when EPOCH is not in TA.EPOCH	Error
<input type="checkbox"/> CDISC.SDTMG.C00026	Trigger error when -TPTREF = null and -RFSTOTC is populated	Error
<input checked="" type="checkbox"/> CDISC.SDTMG.C00029	Trigger error when domain is not an AP-domain and USUBJID is not present in DM.USUBJID	Error
<input checked="" type="checkbox"/> CDISC.SDTMG.C00031	Verify when VISIT is not null in any given domain and VISIT is planned (SV.PRESP = 'Y'), then VISIT should be among TV.VISIT	Error
<input checked="" type="checkbox"/> CDISC.SDTMG.C00032	Verify that visit is planned and exists in TV	Error
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<input checked="" type="checkbox"/> CDISC.SDTMG.C00041	Raise an error when AESCAN, AESCONG, AESDISAB, AESDTH, AESHOSR, AESLIFE, AESOD or AESME = 'Y' and AESER = 'N' or is empty	Error

Rows per page: 25 1 - 25 of 241

Total Rules 241 Total Selected Rules 239

Choose Dictionaries

Validate

## View Report step

"Save and Open" button

- After validation is completed "Save and Open" button becomes available
- Clicking on it saves the report to the download and opens excel report

### Validation

✓ Choose Datasets — ✓ Choose Rules — ✓ Validate — ✓ View Report

View Report

#### THE REPORT IS READY

Data Model: SDTM  
Date and Time: 24.01.2023 16:12  
Number of Datasets: 3  
Number of Rules: 239  
Number of Issues: 27

Save and Open

[Start New Validation](#)

# About Us

- This page displays general information about the app and allows to open a user guide, contact support or view the license (not ready)

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About Us



**EPAM-CDISC-ELECTRON**

Version 0.5.0

CDISC Rules Engine Version 0.5.1

Short explanation text about App. How often it is synced with CDISC by default.

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