The CORE dashboard has 5 widgets

- Conformance Validator: brings you to the heart of the CORE tool where you can perform a validation on the available data
- Rule Editor
- Plugin
- Recent studies: where you can view the most recent studies and validations
- Resources: a link to the user manual

The left pane of the dashboard can be collapsed to have a better and larger view of the dashboard and other screens to follow. Once collapsed only the icons will remain visible which are also clickable to go to other screens.

When you click on View My Studies in the left pane it will direct you to the screen with the available studies.

Two studies have been created in the production environment of MVP 1.0. The first study (CDISCPILOT01) is the Metadata Submission Guidelines data that can be downloaded from the CDISC website, the second study (CDISC-TEST) is the data that was created as part of the CDISC360 project. Clicking on one of the studies will open the study and show the associated data bundles. There is currently an unlimited number of studies that can be created and an unlimited number of data bundles that can be associated with a study. The bundle with the most recent activity will be shown on the left.

On this screen you can see two different eye icons. One is present next to the study and one is present next to the bundle. Clicking the icon next to the study will bring you to the details of the study.
Study Details

At the time of set-up the following information was added to the study:

- Name of the study. For this study we have chosen to use the value of STUDYID. Any value can be chosen as there is no check that will compare the value of Study with the value of STUDYID.
- Study Start Date: this information is matching with the information in the TS domain.
- Therapeutic Area: when setting up, a study a pre-populated list of disease area's are available in a drop-down, however we have chosen to populate it with the value that has been completed in TSVAL for TSPARMCD THERAREA.
- Phase: the Phase of the study is matching the value in the TS domain. When setting up the study, a drop-down list is available with all possible values from the CDISC CT for code list TPHASE.
- Client: this is a free-text field that can be completed with the value of
  - If you are working for a CRO, you can add the name of the biotech or pharma company you are performing the work for
  - If you are working for a pharma or biotech, you can add the name of the CRO that is performing the work.
- Study title: has been completed with the value found in the TS domain for TSPARMCD TITLE.

On the right you can see the 2 bundles that are associated with this study. On the cards you can see the name of the bundle, the standard, and the last validation date. By clicking on the eye icon, you will see 3 tabs of which the first one are the details of the bundle.

At the bottom of the screen there is a back button that brings you back to the main screen of View My Studies. On that screen you will see the same cards as you could see in the study details screen. You can click the eye icon to see the details of the bundle.

Bundle Details

Details

The following details have been added to the bundle:

- Name of the bundle: a free-text field so you can choose any name.
- Standard and version: as part of MVP1.0 only SDTMIG 3.4 has been included.
- Define-XML version: to be able to do crosschecking between data and metadata a Define-XML can be uploaded.
CDISC CT: this is linked with the CDISC Library so all available versions of the CDISC CT can be chosen. When selecting an SDTM study, only 1 version of SDTM CT can be selected but if it is an ADaM study, both an SDTM and an ADaM CT can be selected which can also be different.

WHODrug and MedDRA version are not available as no dictionaries have been uploaded

Comment: additional information can be added to the data bundle

On the right, 4 cards are available which provide you basic information that has taken straight from the datasets. At this moment, only the number of datasets is available. In the future, the number of subjects, records, and sites will also be provided.

Datasets

In the second tab you can the different datasets that have been uploaded or that are available for this bundle. The tab contains the name and label of the datasets, the number of records, size of the datasets and the modification date (the date that the xpt file has been modified).

Reports

In the third tab we can see the reports that have been generated.

In this tab we can see the different validation report that have been ran for this bundle. It gives an overview of the number of issues generated for each severity. This way you can follow up on the progress of the quality of the data over time as you would expect that the number of issues would decrease over time. All reports generated will remain available but they can also be deleted by clicking on the delete button. Next to the delete button there is a download button to generate an Excel version of the report.

You can go to the Conformance Validator by clicking on the icon on the dashboard or on the left pane. Once you click on it you will see the 'Choose Data Bundle' screen.

Choose Data Bundle

This screen is similar to the view my studies screen. The difference is that you will see different icons. You will see the same eye icons to see the details of the study and the details of the data bundle. This is to verify whether you are selecting the correct study and/or bundle.

You can select a data bundle that you want to process for validation by clicking on it. Once the data bundle has been selected you will be directed to the next screen where you can choose your datasets.

Choose Datasets
On the top of the screen you can see a card that has the details of what you will be validating: the study, data bundle, the standard and if completed, the last time the bundle was validated.

If your screen is too small and you want to see more, you can click on the 2 arrows on the right which will expand your screen and hide the card on top. Before going to the next step you need to select the datasets for validation. By default all datasets will be selected but you can choose to select only a subset of datasets. You also have a search field to search for certain parameters like dataset, label, size and number of records, or you can enter any parameter and it will search the whole page on your parameter. Once you have selected the datasets you would like to validate, you can click on the next button.

**Configure Conformance Rules**

In the next screen you configure your conformance rules. On top of the list of conformance rules you see the standard you are running the rules for. The engine is taking the information of the bundle and populates the standard and the version. By default the publisher is selected as “CDISC” but you can add additional publishers in case you want to run the FDA, PMDA or NMPA rules on top of the CDISC Conformance Rules.

Below the rules you can see the controlled terminology that is associated with this bundle. If you want to change the version of CDISC CT you can select a different version from the list. The list of CT is coming directly from the CDISC Library. Other dictionaries or references are not available yet but can be added in a later version.

**Conformance Rules**

The list of rules that can be visualized is fairly small but by clicking on the 2 arrows on the right, the information above and below the table will be hidden.
By default all rules are selected but a subset of the rules can be selected, depending on what you want to validate. You can select and deselect rules by using the tick boxes. On the top of the screen, you can find a search button for which you can use the following parameters: RuleID, Rule Type, Description, Version and Severity. On the right you can find 2 filter buttons. You can filter the list on Rule Type and/or on Rule Severity. With the round arrow next to the filter fields you can reset the filters. In case you are creating a subset of rules that is useful for you in the future, you can save this subset by clicking on the "Save Rule Set" button. The different rule sets that have been saved will be visible in the "My Rule Set" drop-down list. The rule sets can also be deleted but cannot be modified yet at this moment.

Once you have defined the set of rules that you would like to use, you click on the validate button. As soon as the button has been clicked, it will become grey to avoid that the button is clicked multiple times.

Validation
When the validate button has been clicked, the engine will take the rules from the CDISC library and process them on the selected datasets. As soon as the validation has been started, the screen can be closed and other tasks can be performed within CORE. The report will become available in the reports tab of the Data Bundle. When the validation has finished the screen will indicate that the validation was successful and the Open Report button will become available. When clicking on the "Open Report" button you will be redirected to the Reports section of the Data Bundle.

The report details has 3 different tabs

### Issue Summary

In the Issue Summary you can see the list of issues per domain and per Rule ID. An error message is displayed to give information on what is wrong in the data. It provides an overview of the number of issues that are encountered for that specific dataset and Rule ID. There is a possibility to give an explanation for the encountered issue by clicking on the pencil button. As separate screen will pop up where you can provide the explanation. The explanation will be saved in the database in the background and will be linked to the issue. When a new report will be run and the issue is still present, the explanation will remain available so that the issue does not need to be verified anymore.

### Explanation

This issue needs to be resolved

The explanation will be saved in the database in the background and will be linked to the issue. When a new report will be run and the issue is still present, the explanation will remain available so that the issue does not need to be verified anymore.

On top of the screen you again have the possibility to search certain issues on a variety of parameter or you can use the filter button on the right which gives drop down lists of the datasets with issues and the severity.

### Issue Details
The issue details tab gives the overview of all issue per RuleID and per domain. The issue can be looked up as there are additional details available like the USUBJID, record number and the sequence number. To have a good understanding of the issue, an additional set of variables and associated values has been provided.

Rules Report

In the rules report you can find the overview of all rules that have been selected and run and whether the rule ran successfully or whether it has been skipped. A rule can be skipped by the engine if a certain prerequisite has not been fulfilled, like the availability of a certain variable.

Excel Report

When clicking on the download button, an Excel version of the report will be downloaded in the Download folder of your computer. The Excel has 4 different tabs

- Conformance Details
- Issue Summary: similar to the GUI interface
- Issue Details: similar to the GUI interface
- Rules Report: similar to the GUI interface

Conformance Details
The conformance details give you the overview of the study and bundle that has been validated and some of the properties that are associated in CORE. On this screen you can also see how long it took for the selected rules to run on the selected datasets.

In case there is any issue with the validation there is a Transaction ID. This Transaction ID can be used to communicate with CDISC and report the issue.

CDISC is welcoming any feedback on this MVP. The feedback can be taken into consideration by the Roadmap Board. All feedback can be provided via http://www.cdisc.org/contact and select CORE.