



2023

US

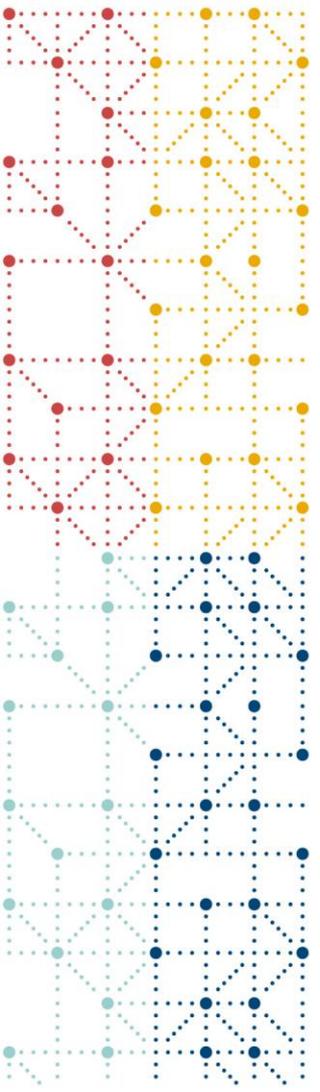
INTERCHANGE

FALLS CHURCH, VA | 18-19 OCTOBER



## CORE Workshop

Presented by Gerry Campion, CDISC  
Amy Palmer, CDISC



# Agenda

Exercise 1

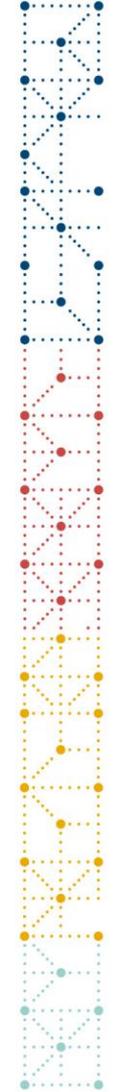
Exercise 2

Exercise 3

Exercise 4

Exercise 5

Exercise 6



Link to Workshop Materials and Zoom Meeting Info

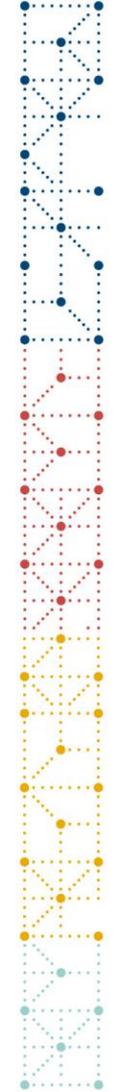
<https://tinyurl.com/cdiscusi2023>

Meeting ID: 848 0164 0226

Passcode: 011415

# Exercise 1 – Accessing the Training Rule Editor

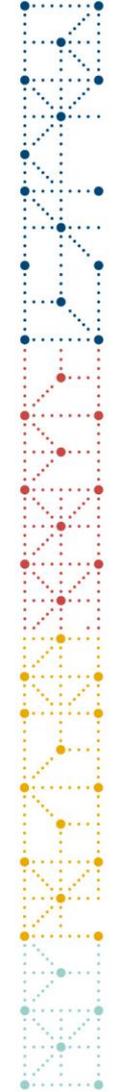
1. Open a web browser
2. Navigate to <https://training-rule-editor.cdisc.org/>
3. Login using CDISCid



## Exercise 2 – CDISC Conformance Rule CG0570

Execute a CDISC conformance rule CG0570 to check whether the ARM variable in the DM dataset is equal to 'Screen Failure,' 'Not Assigned,' 'Unplanned Treatment,' or 'Not Treated.'

1. Log in to CORE Rule Editor
2. Find CG0570
3. Load negative test data
4. Run rule against negative test data
5. Review results



## Questions – Exercise 2

1. Is this rule written as success or failure criteria?
2. What makes this test data negative?
3. What would make this test data positive?

## Exercise 3 – Study Specific Data Quality Check

Assuming we are dealing with a prostate cancer trial, as the study data manager, you want to check if there are any records in the DM dataset where the SEX variable contains non-male subjects.

Steps:

1. Using the rule editor, insert this under the Check block:

```
all:  
  - name: SEX  
    operator: not_equal_to  
    value: M  
  - name: SEX  
    operator: non_empty
```

2. Insert negative test data into the test data template, e.g., “U” and/or “F” into the SEX column

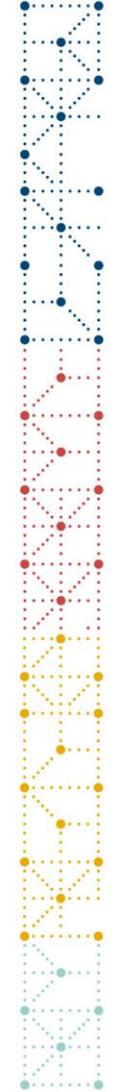
3. Run rule against negative test data

4. Review results

5. As a take-home exercise, think about expanding negative test data to SEX = MALE, which would also result in rule firing, so even though the subject is male, the codelist value is incorrect and would test the logic “SEX not\_equal\_to M”

## Questions – Exercise 3

1. Why is this rule split into 2 conditions?
2. Why is the value set to “M”, rather than “Male” or “MALE”?



## Exercise 4 – Study Specific Data Quality Check

As the study data manager, you want to check if there are any records in the DM dataset where participants are younger than 18 years of age or greater than 85 years of age per the study's inclusion criteria listed below.

Age between 18 and 85 years inclusive.

1. Copy the rule created for Exercise 3 and create a new rule in the rule editor
2. Modify the Rule Description and Outcome Message to align with the focus of the rule
3. Review the CORE Rules Reference Guide to determine the correct operator for this rule
4. Draft the rule in the rule editor
5. Test the rule with the positive and negative test data

## Questions – Exercise 4

1. Which operators should be used to accurately test this rule?

# Exercise 6 – US FDA Technical Rejection Criteria

Develop a rule in the CORE Rule Editor to check that a study start date is present in the data submitted for a study.

[Study Data Technical Conformance Guide - Technical Specifications Document | FDA](#)

1. Determine which dataset needs to be checked to determine the study start date
2. Determine which variable combinations identify the study start date
3. Determine which rule operator(s) are needed to check for a study start date
4. Copy FDA rule template from the CORE Rule Editor
5. Create rule logic, complete rule scope
6. Draft Rule Description and Outcome Message
7. Create positive and negative test data
8. Test rule using both positive and negative test data

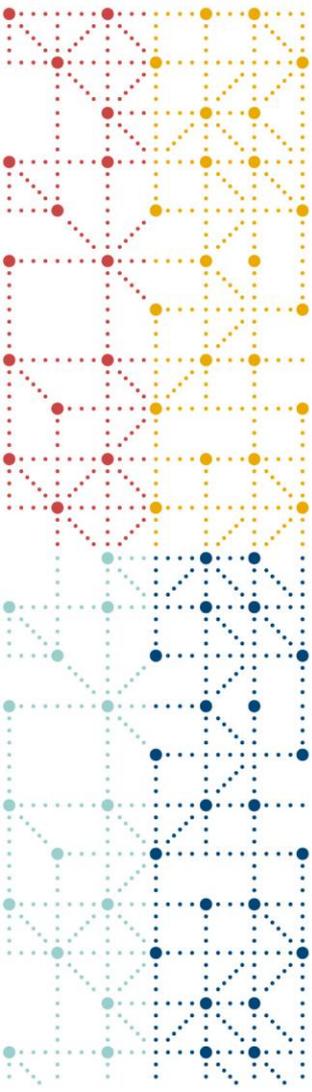
## Exercise 5 – Study Specific Check – Exclusion Criteria

As the study data manager, you want to check if there are any records in the QS dataset where participants the Total Score at the Screening Visit is  $>25$  per the study's exclusion criteria listed below.

1. Copy the rule created for Exercise 3 or 4 and create a new rule in the rule editor
2. Modify the Rule Description and Outcome Message to align with the focus of the rule
3. Review the CORE Rules Reference Guide to determine the correct operators for this rule
4. Draft the rule in the rule editor
5. Create positive and negative test data to determine if the rule is performing as expected
6. Test the rule with the positive and negative test data

## Questions – Exercise 6

1. How can you determine that this rule is an FDA rule within the CORE Rule Editor?
2. How can you determine the source of the rule?



**Thank You!**

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**cdisc**