Data Surveillance:
Use AI Reconciliation

Welcome

Welcome to Data Surveillance: Use AI Reconciliation eLearning.

Note: Please be sure to turn on your speakers as this course is fully narrated. If you do not have speakers, please click the Transcript to follow along.

Objectives

In this course, you will learn about:
- Introduction to AI Reconciliation and its Purpose
- Roles and Permissions

For the role - View AI Reconciliation Reports:

- How to View and Access AI Reconciliation Reports
- How to Interpret AI Reconciliation Reports, and
- How to Manage AI Reconciliation Reports

And

For the role - Configure AI Reconciliation Reports:

- How to Configure AI Reconciliation Reports with Event Analysis, and
- How to Configure AI Reconciliation Reports with Lab Measurements mapping

Introduction

AI Reconciliation enables users with faster and more consistent review of the key safety domains, such as adverse events, reactogenicity, concomitant medication, concomitant procedures, and ongoing medical history. The expert-based models help users in virtual assistant capacity identify potential missing and inconsistent data. There are currently 8 standard reports available to provide users with the list of missing concomitant medications, adverse events, overlapping events, events labeled as worsened without underlying condition, invalid CTCAE grade, and missing labs for CTCAE Grades.

Roles and Permissions

Industry roles such as data managers, and clinical operations teams can use the AI Reconciliation reports.

As a user, you must have "View Data Reviewer" permission and "Submit Queries" to be able to submit queries assigned to your customer-defined platform role to view AI Reconciliation Reports.

And, you must have "Manage Detect CSM Configuration" assigned to your customer-defined platform role to configure AI Reconciliation Reports.

Select the topic based on your role.

View AI Reconciliation Reports

View and Access AI Reconciliation Report

Under the Data Surveillance tab, navigate to AI Reconciliation.

Click each to learn more.

Tabs

Upon landing, you can see two tabs- Conditions and Treatments.

Select a Report

From the dropdown menu, you can select a report. There are 6 reports under Conditions and 2 under Treatments.

Information Icon

The icon gives you brief information about AI Reconciliation.

Overview of AI Reconciliation Reports

Let's look at the overview of each report. Click each link for more information.

Overlapping Conditions- This report shows a list of patient data records that have specific, overlapping conditions recorded multiple times, where the condition records have the same coded term, and overlapping start and end dates.

Conditions without Treatments - ~~This report shows a list of patient records for patients that have conditions without any associated treatment between condition start and end date.~~ This report shows a list of patient records for patients with conditions that require treatment in the form of medication or procedures but have no associated treatment between the condition start and end date. Whether a condition requires treatment, and if so, what kind, is retrieved from the Treatment ConMed and Treatment ConProcedure fields configured by the user. If the user does not configure these fields, it is assumed that all conditions require some kind of treatment.

Worsening Conditions - This report shows a list of patients with conditions identified as worsening, but either do not have any associated ongoing medical history (or MH) or non-worsening conditions before the worsening condition start date, OR have non-worsening conditions reported after the worsening condition start date.

Overlapping non-worsening Conditions and ongoing MH - This report shows a list of patients with non-worsening conditions that occur within the patient's ongoing medical history

Overlapping Treatments - This report shows a list of patients with two or more of the same treatment whose start and end date overlap.

Treatments without Conditions or ongoing MH- This report shows a list of concomitant treatments that do not have any associated ongoing medical history or conditions that were recorded. The treatment start date should be within the condition's start and end date. Please note that prior CMs which ended before the patient started the trial and prophylaxis treatments such as vitamins and birth control, are not considered in this report.

Invalid CTCAE Grade - This report uses CTCAE version 5 to identify discrepancies in the Adverse Event records for which the grade was entered but has anomalies. Anomalies are divided into 3 types of descriptions:
- Grade is present but not required
- Grade is not present but required, or
- Grade entered was invalid

Missing Lab for CTCAE Grade - This report uses CTCAE version 5 to identify discrepancies in AE records for which the CTCAE grade was entered, but the relevant labs are not recorded between the start and end timeframe.
- High Confidence means that there was no lab within the same timeframe

- Medium Confidence means labs were found within the same timeframe but did not match the lab requirement for given grade
- Low confidence means labs were found within the same timeframe but there is not a 100% match on required lab analyte name and specimen type to the panel name.

Review AI Reconciliation Report Findings

Click the thumbnail to view the show me video on how to interpret data using AI Reconciliation report.

Let's select the "Conditions without Treatments" report for this demonstration. This report shows a list of patients with conditions that do not have any concomitant medications recorded in a certain time period from the start date of the adverse event. For more information about the report, you can click on the information icon.

You will also see an individual report status which shows either the successful status of the last report refresh, or a failure status due to incorrect configuration. Please note that if a report shows a failed status, you will still be able to access the results of the other successfully refreshed reports.

Logline

On each AI Reconciliation report, you can see a logline column that shows the variable referencing the corresponding logline row in the RAVE EDC, enhancing the efficiency of data tracking and validation.

Same Time Frame Treatments

Let's look at the "Same Time Frame Treatments" value. Click the value under this column for the patient.

This lists the treatment taken by that patient within the same time frame as the reported condition. The algorithm doesn't show if the treatment is related to the reported condition, however, it lists them for you to review and you can link the treatment to the condition from here if it's related to the condition. Once linked, that finding and any other finding with the same treatment and condition pair occurring in the same timeframe are now assigned "low" confidence.

~~Click on the thumbs-up icon if the system generated algorithm is correct and the condition does not have an associated treatment. When you click thumbs down or link the treatment to the condition, it gives a Low status under the Confidence column to indicate that the algorithm is incorrect and the treatment and condition are related. The patient will also be marked as reviewed.~~

Click on the thumbs-up icon if the system-generated algorithm is correct and the condition does not have an associated treatment. If you click thumbs down, the patient is marked as reviewed, but it does not affect the Confidence score. When you link the treatment to the condition within the same timeframe, the Confidence column for linked pairs will show a Low status after refresh, indicating that the algorithm was incorrect and the treatment and condition are related. Note this update happens only within the study and is not generalized for other studies.

The high, medium, and low under Confidence column indicates the confidence level the algorithm assigns to potentially related conditions, treatment, and medical history within a record.

Outside Time Frame Treatments
Click the value under this column for the patient. This lists the treatment taken by that patient that is related to the condition but outside of the condition time frame. In this example, the patient took Doxazosin medication for Hypertension and took the treatment on Aug 10th. The condition is reported on July 10th. This shows that the treatment was taken outside of the condition event time frame. Note: Linking treatment and condition pairs in the outside timeframe will not have any impact since they are still considered related but outside time. If there is discrepancy we suggest opening a query to get the date resolved.

Using Filters in AI Reconciliation Reports

Let's use the "Conditions without Treatments" report for this demonstration. Upon selecting the report, you can view all unreviewed patient data. The drop-down helps you navigate to reviewed or all patients. You can filter the report via these criteria.

Download Reports

On any AI Reconciliation report, you can click the Download button to save the report as a CSV file to your local drive.

Downloaded Files

Downloaded AI Reconciliation reports have two files:
- AI Reconciliation Report Data File, in which the first column is for the record ID, providing a unique identifier for each record.

- AI Reconciliation Report Comment File, which uses the record ID column to associate comments with the corresponding record in the data file, ensuring accurate and organized feedback.

Audit History

The reverse clock icon on the top of the page shows audit history. It shows a record of who and when someone marked a record as reviewed, provided feedback on a record, or linked a record. You can filter the audit data by start and end date and can export the audit report from here.

Refresh Data

You can click the Refresh Data button to capture any work completed since the last refresh before you start working on the reports.

Mark Reviewed

Click each to learn more.
1) **Mark Reviewed-** You can click Mark Reviewed once you review the patient information.
2) **Bulk Mark Reviewed**- You can also mark the patient as reviewed in bulk, by selecting multiple patient IDs and Mark Reviewed or can select all patients by clicking the checkbox on the top of Patient IDs and then Click Mark Reviewed.
3) **More Icon-** If there is a change in patient data, you can click the More icon and select Mark Unreviewed and then navigate to the Patient ID hyperlink which takes you to the Patient Profile for further investigation.

Mark Unreviewed & Comment
Click each to learn more.
- Mark Unreviewed - If there is a change in patient data, you can click the More icon and select Mark Unreviewed and then navigate to the Patient ID hyperlink which takes you to the Patient Profile for further investigation.

- Comment - Comments enable you to share review notations with your study team. Once you add a comment, the Status column shows a Comment icon, where you can click and view the comment history.

Submit Queries

To submit queries, select the patient and click Submit Queries. You can see the standard query text for every report. You can update the query text by clicking the More icon and selecting Edit Query.

Note: You can use up to 1,084 characters when creating queries, which allows you to include more detailed and comprehensive information in the clinical data queries.

Update the text and click Apply. This creates a query record in Rave. You can view the open queries for a patient under the status column.

Note: The study and the URL need to be onboarded in order to send the queries to Rave. Contact Medidata personnel to enable Rave to your study and URL.

Knowledge Check

1. Conditions without Treatment report shows a list of patient records for patients that have conditions without any associated treatment between condition start and end date.

Select the correct answer.

A. True
B. False

2. AI Reconciliation Report Comment File uses the Patient ID column to associate comments with the corresponding record in the data file.

Select the correct answer.

A. True
B. False

Summary

In this course, you have learned about:

- Introduction to AI Reconciliation and its Purpose
- Roles and Permissions
- How to View and Access AI Reconciliation Reports
- How to Interpret AI Reconciliation Reports, and
- How to Manage AI Reconciliation Reports

Thank you for completing the course. To end the course, please exit the browser window.

Configure AI Reconciliation Reports - Event Analysis

To configure AI Reconciliation Reports, navigate to the Data Surveillance tab. In the left hand navigation, expand the Configuration option, and then click Data Mapping. Select the Event Analysis Mapping tab.

With event analysis mapping, you can configure data sets and variables that Data Surveillance consumes to produce the algorithms for AI Reconciliation reports.

To edit the mapping of an existing data set, click the name of the data set in the Event Analysis Mapping table.

To create a new mapping for a data set, click the "New Mapping" button.
- Condition Mapping will map data sets and fields which record conditions such as Adverse Events or Reactogenicity. Based on the condition mapping, Event Incidence, Under-Over Reporting, and AI Reconciliation reports identify which data set to check for event analysis.
- Treatment Mapping will map data sets and fields which record patient's treatments like Concomitant Medication or Concomitant Procedure. Based on the treatment mapping, AI Reconciliation's reports such as "Conditions without Treatments", "Worsening Conditions", and "Overlapping non worsening conditions and Ongoing MH" will identify which data set to check and whether the condition was treated.
- History Mapping will map data sets and fields to report on the patient's medical history. Based on the history mapping, AI Reconciliation's reports such as " "Conditions Without Treatment", "Worsening Conditions", and "Overlapping Non Worsening Conditions and Ongoing MH" will identify which data set appears in the reports.

Each mapping selection will have different field options. Click the following mapping options to learn more.

Condition Mapping
- Data Set - You can select the Data Set to run the event analysis on
- Term - Reported term for condition
- Start Date - Start Date for the Condition
- Serious Event (Optional) - Defines whether the condition was serious
- End Date - End Date for the Condition
- Treatment ConMed (Optional) - Whether concomitant medication is used for treatment
- TreatmentConProcedure (Optional) - Whether concomitant procedure is used for treatment
- Grade (Optional)- CTCAE grade
- Enable For - Use the selection boxes to select the reports you want the event analysis mapping to appear in

Treatment Mapping
- Data Set - Data set that should be used when the event analysis runs
- Term - Reported term for treatment
- Start Date - Treatment start date
- Indication - Treatment indication

- End Date - Treatment end date
- Concomitant Treatment Type - Select "Medication" if in Condition Mapping you mapped to Treatment ConMed. Select "Procedure" if in Condition Mapping you mapped to Treatment ConProcedure.
- Enable For - Use the selection boxes to select the reports you want the event analysis mapping to appear in

History Mapping
- Data Set - Data set that should be used when the event analysis runs
- Term - Reported term for treatment
- Ongoing - Select whether the medial history is an ongoing event

Configure AI Reconciliation Reports - Lab Measurements

With Lab Measurements mapping, you can configure data sets and variables that Data Surveillance consumes to produce the algorithms for the CTCAE Grade reports. Navigate to Data Mapping under Configuration in the left hand navigation. Select the Lab Measurements tab.

Click each to learn more.

- Add Lab measurements - A new line will appear within the table. Use the Dropdown menus to select a data set, collection date, sample type, and Analyte name.
  Click to learn more.
  - Dataset – Adverse event data set you want the AI Reconciliation algorithm to use to run its analysis on to show data in the CTCAE reports
  - Collection Date – Date on which laboratory measurements were collected
  - Sample Type – Type of biological matter collected in the laboratory from patients to conduct tests
  - Analyte Name – Data set variable that corresponds to the type of specific substance or chemical being measured in the laboratory test
  You can also complete the optional attributes for further specification.
  Click to learn more.
  - Analyte Value (Optional) - Data set variable value that corresponds to the analyte
  - Analyte Unit (Optional) – Unit in which the analyte variable value measured
  - Upper Limit (Optional) – Highest analyte value permissible
  - Lower Limit (Optional) – Lowest analyte value permissible
  - Loinc Code (Optional) – Analyte code as per the Logical Observation Identifiers Name and Codes database

  When you are finished, click the Save button.

- Edit Lab Measurement Data Set - You can also edit an existing lab measurement mapping by adjusting any editable dropdowns in the row, and then click the Save button.
- Remove Lab Measurement Data Set - Click the X icon at the end of the row. You will see a pop up message to warn you that the system will clear configuration data. Click the "Delete" button to confirm the removal.

Note: CTCAE grades in conditions mapping and laboratory measurements are both required to be mapped to run two CTCAE reports.

Knowledge Check

1. Treatment Mapping maps data sets and fields that record conditions such as Adverse Events or Reactogenicity.

Select the correct answer.

A. True
B. False

2. Which of the following involves configuring data sets and variables used by AI Reconciliation algorithms for CTCAE Grade reports?

Select the correct answer.

A. Lab Measurements mapping
B. History mapping
C. Treatment mapping
D. Event Analysis mapping

Summary

In this course, you have learned about:
- Introduction to AI Reconciliation and its Purpose

- Roles and Permissions

- How to Configure AI Reconciliation Reports with Event Analysis; and
- How to Configure AI Reconciliation Reports with Lab Measurements mapping

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