

# Comparing Medical Queries with Interactive Graphics using JMP Clinical

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## ABSTRACT

For years pharmaceutical organizations and regulatory agencies relied on the MedDRA organization to provide Standardised Medical Queries (SMQs) to group similar adverse events into a health issue or disease state. Now the FDA has released their own Office of New Drugs Custom Medical Queries (OCMQs) along with algorithmic queries to the public as an alternative way to group similar adverse events into a medical condition. In addition to the OCMQs, the FDA released the Standard Safety Tables and Figures Integrated Guide with some examples of how to display the medical queries. Using those examples as a guide, interactive features can be added to the tables and figures to explore safety signals and make comparisons between OCMQs and SMQs. This paper will discuss how JMP Clinical uses filtering, dynamic options, hover labels, and drilldowns as interactive features to detect safety signals from adverse events and medical queries.

## INTRODUCTION

Medical queries are groupings of adverse events into medical conditions that provide a standard way to assist with identifying safety issues. Each adverse event contributing to the medical query is assigned either as part of the narrow scope or part of the broad scope. Narrow queries contain specific terms that provide high probability the condition occurred, while broad queries are less specific and provide reasonable assurance the condition occurred (U.S. FDA & Duke, 2022).

There are three types of medical queries commonly used: Standardised MedDRA Queries (SMQs), Office of New Drugs Custom Medical Queries (OCMQs), and custom medical queries (CMQs). SMQs are provided by MedDRA as ASCII files and can be downloaded through a MedDRA account. OCMQs are available through the FDA website as an Excel File. CMQs are sponsor defined queries typically stored in the ADAE domain.

In April 2025, the FDA released the Standard Safety Tables and Figures: Integrated Guide to help sponsors in writing reports for submission. This guidance is used by JMP Clinical to design the tables and figures included in the interactive reports. For the medical query reports in JMP Clinical, this mainly includes forest plots with frequencies and risk differences and tables with counts, percentages, and risk differences. JMP Clinical takes this guidance to the next level by using interactive features to allow for dynamic exploration of the data.

## MERGING MEDICAL QUERY FILES WITH ADVERSE EVENT DATA

### STANDARDISED MEDDRA QUERIES

Four ASCII files are needed from MedDRA to map adverse events to the appropriate medical queries: smq\_list, smq\_content, pt, and llt. The first two columns of the smq\_list file contain the SMQ code and the SMQ name, respectively. The first four columns of the smq\_content file contain the SMQ code, the term code, the term level, and the term scope, respectively. By merging these two files based on the SMQ code, a new file is created with both the SMQ name and the scope of the query to categorize the query as either broad or narrow.

Next, the pt file and the llt file are merged by the preferred term code to get both the preferred term name and the lower limit term name in the same file. This file can then be merged with the combined smq\_list and smq\_content file by the preferred term code found in both files. The resulting file contains a map of the medical query term, scope, preferred term, and lower limit term that can be merged with the adverse event data from a given study.

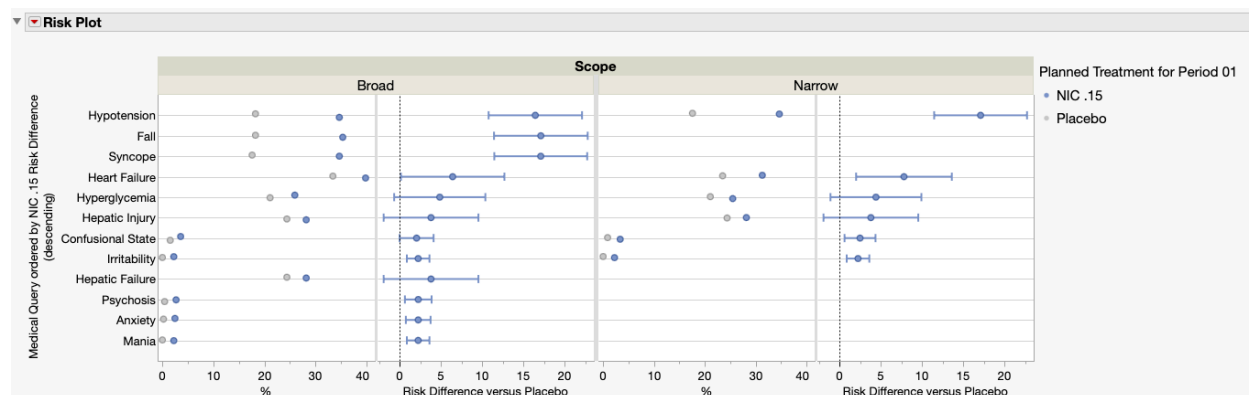
### OFFICE OF NEW DRUG CUSTOM MEDICAL QUERIES

The Excel file provided by the FDA for the OCMQs requires less merging than the SMQ files. In the Excel file, there is a tab called Consolidated List that provides the OCMQ name, preferred term, and scope all in one place. In addition to this tab, the OCMQ Comments tab provides the organ system associated with each query which replaces the system organ class in the adverse event data for any OCMQ analysis. This tab also lists the criteria for any medical queries that contain an algorithm. Depending on the analysis being conducted, the Consolidated List tab can be directly merged with the adverse event data by the preferred term or the Consolidated List tab and the OCMQ Comments tab can be merged first to add in the FDA provided Organ System.

## MEDICAL QUERY FIGURES AND TABLES

Using the FDAs Standard Safety Tables and Figures: Integrated Guide as a reference, JMP Clinical created the Medical Query Risk Report summarizing both SMQs and OCMQs with interactive tables and figures.

At the top of the report is the Risk Plot to give a visual overview of the medical queries by treatment group. The plot is split by broad and narrow scope with a dot plot for percent occurrence and a forest plot for risk difference under each one. Around each risk difference point is a line to represent the 95% confidence interval. A dotted line at 0 represents that there is no difference between the treatment and comparator groups.



Under the plot is a set of four tables each displaying counts and percentages for each treatment group as well as the risk difference with a 95% confidence interval. The first two tables summarize narrow and broad queries by the medical query and the preferred terms that contribute to that medical query.

| Narrow Medical Queries and Terms |                      |                      |                                             |
|----------------------------------|----------------------|----------------------|---------------------------------------------|
| Medical Query                    | NIC .15<br>(N = 447) | Placebo<br>(N = 455) | Risk Difference for<br>NIC .15 over Placebo |
| Hypotension                      | 155 (34.7)           | 80 (17.6)            | 17.1 (11.5, 22.7)                           |
| Hypotension                      | 155 (34.7)           | 80 (17.6)            | 17.1 (11.5, 22.7)                           |
| Heart Failure                    | 140 (31.3)           | 107 (23.5)           | 7.8 (2.0, 13.6)                             |
| Pulmonary oedema                 | 132 (29.5)           | 104 (22.9)           | 6.7 (0.9, 12.4)                             |
| Cardiac failure congestive       | 24 (5.4)             | 17 (3.7)             | 1.6 (-1.1, 4.4)                             |
| Hyperglycemia                    | 114 (25.5)           | 96 (21.1)            | 4.4 (-1.1, 9.9)                             |
| Hyperglycaemia                   | 114 (25.5)           | 96 (21.1)            | 4.4 (-1.1, 9.9)                             |
| Hepatic Injury                   | 126 (28.2)           | 111 (24.4)           | 3.8 (-1.9, 9.5)                             |
| Hepatic function abnormal        | 126 (28.2)           | 111 (24.4)           | 3.8 (-1.9, 9.5)                             |
| Hepatitis                        | 2 (0.4)              | 1 (0.2)              | 0.2 (-0.5, 1.0)                             |
| Hepatomegaly                     | 1 (0.2)              | 0 (0.0)              | 0.2 (-0.2, 0.7)                             |
| Confusional State                | 15 (3.4)             | 4 (0.9)              | 2.5 (0.6, 4.4)                              |
| Delirium                         | 7 (1.6)              | 1 (0.2)              | 1.3 (0.1, 2.6)                              |
| Disorientation                   | 8 (1.8)              | 3 (0.7)              | 1.1 (-0.3, 2.6)                             |
| Irritability                     | 10 (2.2)             | 0 (0.0)              | 2.2 (0.9, 3.6)                              |
| Agitation                        | 10 (2.2)             | 0 (0.0)              | 2.2 (0.9, 3.6)                              |

In these tables, some of the preferred terms display an asterisk next to the name to indicate that those terms fall under more than one medical query. If any such terms are present, then under the table will be a second table listing the terms in multiple medical queries.

| <b>*Terms in Multiple Medical Query</b>          |              |
|--------------------------------------------------|--------------|
| <b>Medical Query and Dictionary-Derived Term</b> | <b>Scope</b> |
| <b>Ascites</b>                                   |              |
| Hepatic Failure                                  | Broad        |
| Hepatic Injury                                   | Broad        |
| <b>Hepatic function abnormal</b>                 |              |
| Hepatic Failure                                  | Broad        |
| Hepatic Injury                                   | Broad        |
| <b>Hyperbilirubinaemia</b>                       |              |
| Hepatic Failure                                  | Broad        |
| Hepatic Injury                                   | Broad        |
| <b>Hypotension</b>                               |              |
| Fall                                             | Broad        |
| Syncope                                          | Broad        |
| Hypotension                                      | Broad        |
| <b>Jaundice</b>                                  |              |
| Hepatic Failure                                  | Broad        |
| Hepatic Injury                                   | Broad        |

The third table summarizes all medical queries with a column indicating whether the query is broad or narrow.

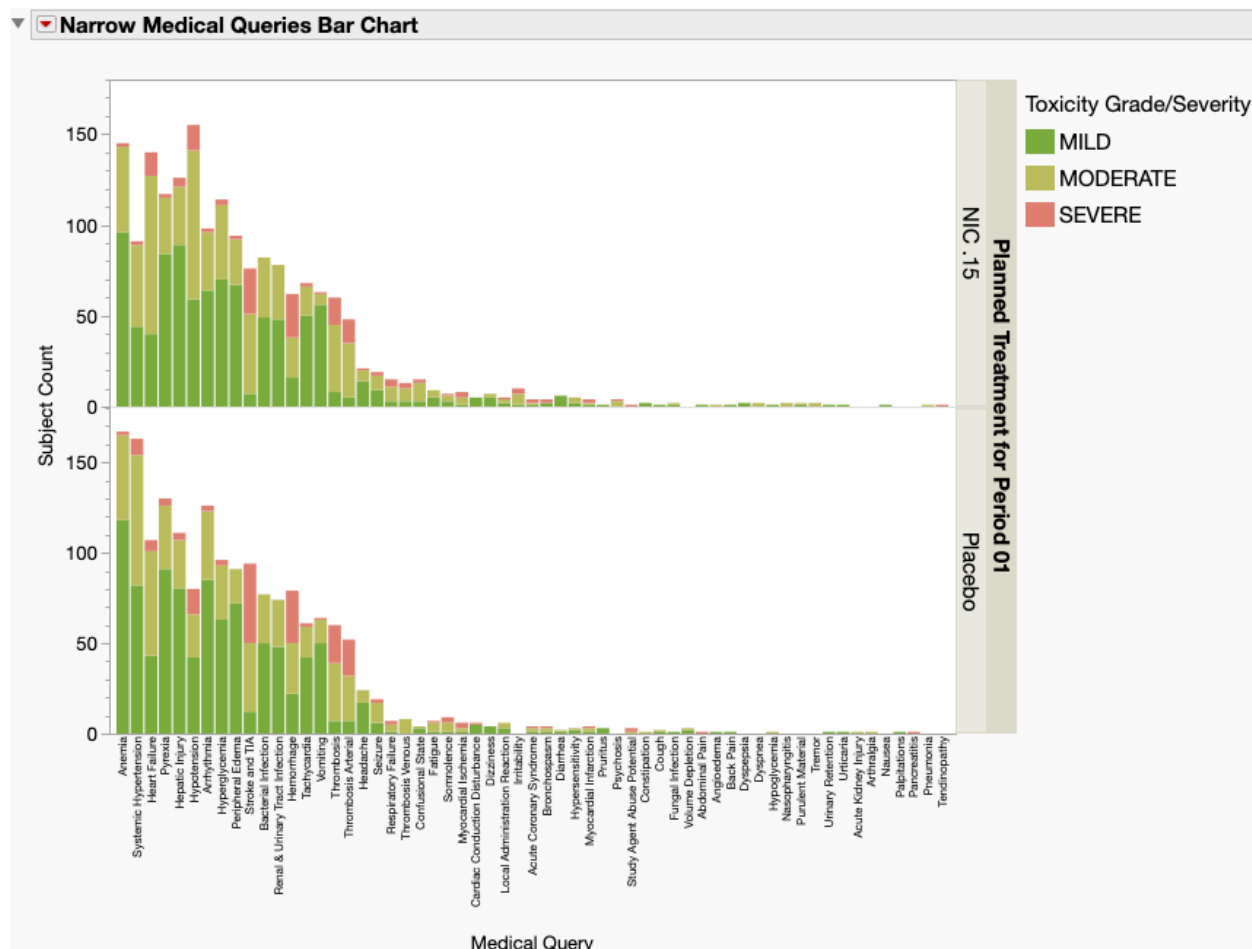
| <b>Medical Query</b> | <b>Scope</b> | <b>NIC .15<br/>(N = 447)</b> | <b>Placebo<br/>(N = 455)</b> | <b>Risk Difference for<br/>NIC .15 over Placebo</b> |
|----------------------|--------------|------------------------------|------------------------------|-----------------------------------------------------|
| Fall                 | Broad        | 158 (35.3)                   | 83 (18.2)                    | 17.1 (11.4, 22.8)                                   |
| Syncope              | Broad        | 155 (34.7)                   | 80 (17.6)                    | 17.1 (11.5, 22.7)                                   |
| Hypotension          | Broad        | 155 (34.7)                   | 83 (18.2)                    | 16.4 (10.8, 22.1)                                   |
| Heart Failure        | Broad        | 178 (39.8)                   | 152 (33.4)                   | 6.4 (0.1, 12.7)                                     |
| Hyperglycemia        | Broad        | 116 (26.0)                   | 96 (21.1)                    | 4.9 (-0.7, 10.4)                                    |
| Hepatic Failure      | Broad        | 126 (28.2)                   | 111 (24.4)                   | 3.8 (-1.9, 9.5)                                     |
| Hepatic Injury       | Broad        | 126 (28.2)                   | 111 (24.4)                   | 3.8 (-1.9, 9.5)                                     |
| Hypotension          | Narrow       | 155 (34.7)                   | 80 (17.6)                    | 17.1 (11.5, 22.7)                                   |
| Heart Failure        | Narrow       | 140 (31.3)                   | 107 (23.5)                   | 7.8 (2.0, 13.6)                                     |
| Hyperglycemia        | Narrow       | 114 (25.5)                   | 96 (21.1)                    | 4.4 (-1.1, 9.9)                                     |
| Hepatic Injury       | Narrow       | 126 (28.2)                   | 111 (24.4)                   | 3.8 (-1.9, 9.5)                                     |

The final table summarizes each system organ class with which medical queries contribute to that system organ class. The table again contains a column indicating whether the query is broad or narrow.

| <b>System Organ Class</b>                            |              |                              |                              |                                                     |
|------------------------------------------------------|--------------|------------------------------|------------------------------|-----------------------------------------------------|
| <b>System Organ Class</b>                            | <b>Scope</b> | <b>NIC .15<br/>(N = 447)</b> | <b>Placebo<br/>(N = 455)</b> | <b>Risk Difference for<br/>NIC .15 over Placebo</b> |
| General disorders and administration site conditions |              | 270 (60.4)                   | 227 (49.9)                   | 10.5 (4.1, 17.0)                                    |
| Fall                                                 | Broad        | 158 (35.3)                   | 83 (18.2)                    | 17.1 (11.4, 22.8)                                   |
| Vascular disorders                                   |              | 209 (46.8)                   | 166 (36.5)                   | 10.3 (3.9, 16.7)                                    |
| Hypotension                                          | Broad        | 155 (34.7)                   | 83 (18.2)                    | 16.4 (10.8, 22.1)                                   |
| Hypotension                                          | Narrow       | 155 (34.7)                   | 80 (17.6)                    | 17.1 (11.5, 22.7)                                   |
| Nervous system disorders                             |              | 254 (56.8)                   | 217 (47.7)                   | 9.1 (2.6, 15.6)                                     |
| Syncope                                              | Broad        | 155 (34.7)                   | 80 (17.6)                    | 17.1 (11.5, 22.7)                                   |
| Endocrine disorders                                  |              | 116 (26.0)                   | 98 (21.5)                    | 4.4 (-1.1, 10.0)                                    |
| Hyperglycemia                                        | Broad        | 116 (26.0)                   | 96 (21.1)                    | 4.9 (-0.7, 10.4)                                    |
| Hyperglycemia                                        | Narrow       | 114 (25.5)                   | 96 (21.1)                    | 4.4 (-1.1, 9.9)                                     |
| Hepatobiliary disorders                              |              | 126 (28.2)                   | 111 (24.4)                   | 3.8 (-1.9, 9.5)                                     |
| Hepatic Failure                                      | Broad        | 126 (28.2)                   | 111 (24.4)                   | 3.8 (-1.9, 9.5)                                     |
| Hepatic Injury                                       | Broad        | 126 (28.2)                   | 111 (24.4)                   | 3.8 (-1.9, 9.5)                                     |
| Hepatic Injury                                       | Narrow       | 126 (28.2)                   | 111 (24.4)                   | 3.8 (-1.9, 9.5)                                     |
| Cardiac disorders                                    |              | 277 (62.0)                   | 292 (64.2)                   | -2.2 (-8.5, 4.1)                                    |
| Heart Failure                                        | Broad        | 178 (39.8)                   | 152 (33.4)                   | 6.4 (0.1, 12.7)                                     |
| Heart Failure                                        | Narrow       | 140 (31.3)                   | 107 (23.5)                   | 7.8 (2.0, 13.6)                                     |

## AN ALTERNATE VIEW

The Medical Query Risk Report requires at least two treatment groups to run so this type of analysis cannot be used for blinded studies or other analyses with only one group. As an alternative, JMP Clinical provides a Medical Query Distribution report summarizing the counts and percentages of medical queries in a bar chart and tables like those on the risk report. The different view allows for more options such as stacking the bar chart and tables by another variable like severity or seriousness.



## JMP CLINICAL INTERACTIVE FEATURES

JMP Clinical is interactive software that allows you to explore clinical trial data with features such as filtering, dynamic options, hover labels, and drilldowns.

### FILTERING

The Medical Query Risk Report includes a report filter to allow for filtering based on medical query name, risk difference, absolute risk difference, and scope. Each of these will filter both the plot and the tables down to only the values selected. For example, if the risk difference is set to 2 or greater, then the plot and tables will update to only include medical queries with a risk difference in that range. Similarly for the absolute risk difference, the plot and tables will update to include medical queries with a risk difference of 2 or greater but also include medical queries with a risk difference of -2 or less. This filter allows the user to view the differences on either side of the spectrum.

The Medical Query Distribution report also includes a report filter, but with different variables. This filter allows for filtering on adverse event characteristics, such as severity and seriousness.

### DYNAMIC OPTIONS

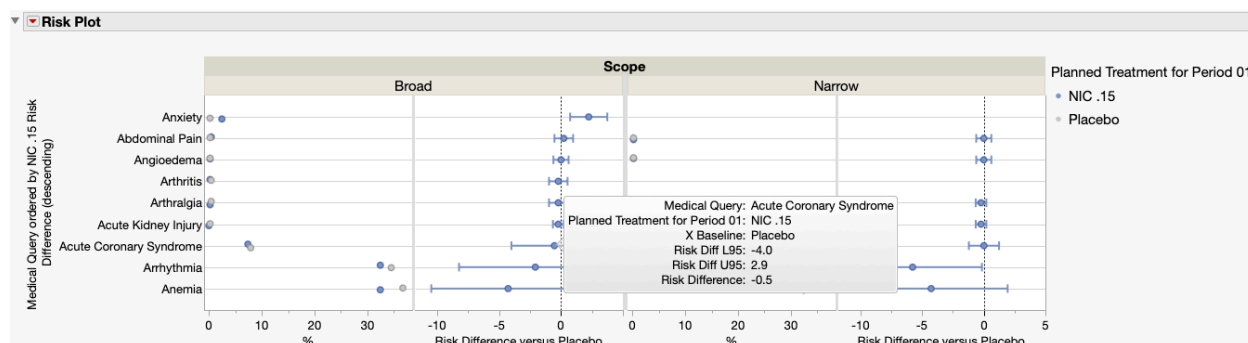
Most JMP Clinical reports include options that automatically rerun the report to display new results. The Medical Query Risk Report includes options for changing the type of data displayed as well as how the data is displayed. The first options allow for switching between SMQs and OCMQs and picking the version of the files to use. The next option is used to pick the event type: all events, pre-treatment events, treatment emergent events, on treatment events, or off treatment events. The remaining options are used to change the display of the plot and tables, including swapping out risk difference for relative risk or odds ratio. In addition, the user can change the risk

difference to be displayed as a percent or a proportion and change the output to be sorted by either risk difference, count, or alphabetically.

In the Medical Query Distribution report, the same options exist for selecting SMQs or OCMQs and selecting event type, but also includes options for selecting the demographic variable, stacking variable, and whether to display results on the graph as counts or percents. The selection for demographic grouping swaps out the value being displayed on the y-axis of the graph and displayed for the columns in the table. By default, the treatment variable is displayed with the option to switch to sex, race, country, study site identifier, or no grouping. The stack option by default is set to none, but can be switched to add seriousness, severity, outcome, causality, or action taken to the graphs and tables.

## HOVER LABELS

One of the interactive features of any JMP graph is hover labels. Placing the tip of the mouse cursor over any point on the graph will pop up a box that displays information such as the medical query name, treatment group, percent occurrence, and risk difference.



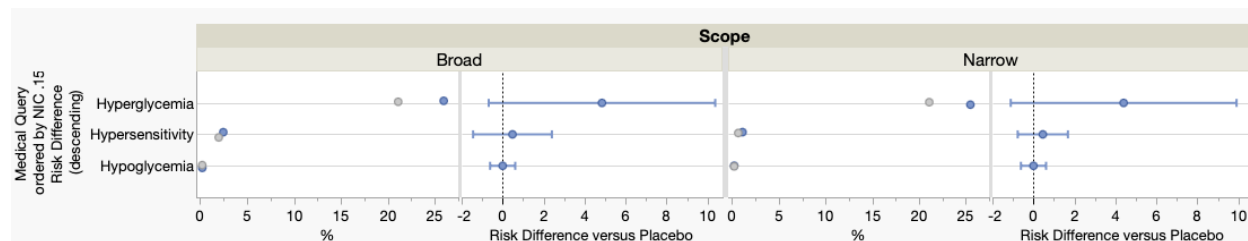
## LISTINGS OF PATIENTS WITH SPECIFIC MEDICAL QUERIES

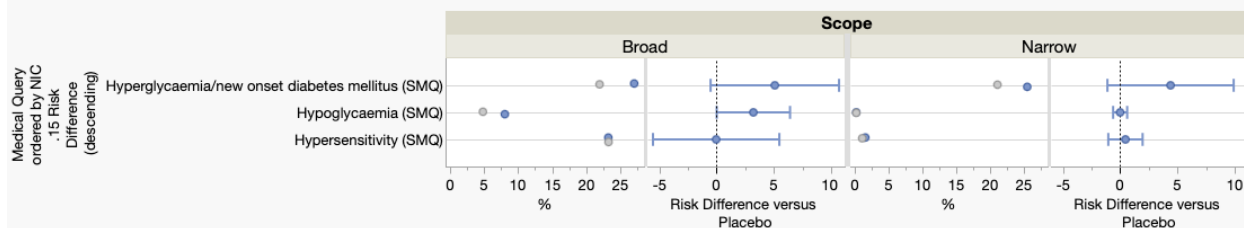
The Medical Query Risk Report also contains a drilldown to a listing of the patients experiencing selected medical queries. By selecting any of the numbers in any of the tables, a listing pops up containing all the subject identifiers for that medical query as well as information on the adverse event. Selecting additional numbers in the tables will add to the listing and deselecting will remove them.

| Table Selections          |                                 |               |        |                         |                    |                                     |               |                         |                                     |                                   |
|---------------------------|---------------------------------|---------------|--------|-------------------------|--------------------|-------------------------------------|---------------|-------------------------|-------------------------------------|-----------------------------------|
| Unique Subject Identifier | Planned Treatment for Period 01 | Medical Query | Scope  | Dictionary-Derived Term | System Organ Class | Reported Term for the Adverse Event | Serious Event | Toxicity Grade/Severity | Study Day of Start of Adverse Event | Action Taken with Study Treatment |
| 231019                    | NIC .15                         | Arrhythmia    | Narrow | Atrial flutter          | Cardiac disorders  | Atrial flutter                      | N             | MODERATE                | 3                                   | DOSE NOT CHANGED                  |
| 322001                    | NIC .15                         | Arrhythmia    | Narrow | Atrial flutter          | Cardiac disorders  | Atrial flutter                      | N             | MODERATE                | 5                                   | UNKNOWN                           |
| 392012                    | NIC .15                         | Arrhythmia    | Narrow | Atrial flutter          | Cardiac disorders  | Atrial flutter                      | N             | MODERATE                | 5                                   | UNKNOWN                           |
| 41026                     | NIC .15                         | Arrhythmia    | Narrow | Atrial flutter          | Cardiac disorders  | Atrial flutter                      | N             | MODERATE                | 6                                   | UNKNOWN                           |
| 441006                    | NIC .15                         | Arrhythmia    | Narrow | Atrial flutter          | Cardiac disorders  | Atrial flutter                      | N             | MILD                    | 1                                   | UNKNOWN                           |
|                           |                                 |               |        |                         |                    |                                     |               |                         |                                     | Outcome of Adverse Event          |
|                           |                                 |               |        |                         |                    |                                     |               |                         |                                     | RECOVERED/RESOLVED                |
|                           |                                 |               |        |                         |                    |                                     |               |                         |                                     | RECOVERING/RESOLVING              |
|                           |                                 |               |        |                         |                    |                                     |               |                         |                                     | FATAL                             |
|                           |                                 |               |        |                         |                    |                                     |               |                         |                                     | RECOVERED/RESOLVED                |
|                           |                                 |               |        |                         |                    |                                     |               |                         |                                     | RECOVERED/RESOLVED                |

## COMPARING MEDICAL QUERIES

Switching back and forth between SMQs and OCMQs allows for comparison of events under both methodologies. For example, hyperglycemia, hypersensitivity, and hypoglycemia are medical queries that occur in both SMQs and OCMQs. When the Medical Query Risk Report is run on our sample Nicardipine data and subset to these three medical queries, it's easy to see that the results for hypoglycemia in the broad scope are quite different. Looking at the risk differences in the risk plot quickly shows that the risk difference for SMQs is much larger than in OCMQs.





The tables for these same queries reveal that the differences are due to which adverse event terms contribute to the medical query. Under OCMQs there is only one adverse event term, but under SMQs there are eight. By looking at this comparison, reviewers can be aided in determining whether a safety signal exists.

#### Broad Medical Queries and Terms

| Medical Query                             | NIC .15<br>(N = 447) | Placebo<br>(N = 455) | Risk Difference for<br>NIC .15 over Placebo |
|-------------------------------------------|----------------------|----------------------|---------------------------------------------|
| Hyperglycemia                             | 116 (26.0)           | 96 (21.1)            | 4.9 (-0.7, 10.4)                            |
| Hyperglycaemia                            | 114 (25.5)           | 96 (21.1)            | 4.4 (-1.1, 9.9)                             |
| Polyuria                                  | 2 (0.4)              | 0 (0.0)              | 0.4 (-0.2, 1.1)                             |
| Gangrene                                  | 1 (0.2)              | 0 (0.0)              | 0.2 (-0.2, 0.7)                             |
| Hypersensitivity                          | 11 (2.5)             | 9 (2.0)              | 0.5 (-1.4, 2.4)                             |
| Type III immune complex mediated reaction | 5 (1.1)              | 3 (0.7)              | 0.5 (-0.8, 1.7)                             |
| Status asthmaticus                        | 4 (0.9)              | 4 (0.9)              | 0.0 (-1.2, 1.2)                             |
| Laryngeal oedema                          | 1 (0.2)              | 1 (0.2)              | 0.0 (-0.6, 0.6)                             |
| Urticaria vesiculosa                      | 1 (0.2)              | 1 (0.2)              | 0.0 (-0.6, 0.6)                             |
| Hypoglycemia                              | 1 (0.2)              | 1 (0.2)              | 0.0 (-0.6, 0.6)                             |
| Hypoglycaemia                             | 1 (0.2)              | 1 (0.2)              | 0.0 (-0.6, 0.6)                             |

#### Broad Medical Queries and Terms

| Medical Query                                    | NIC .15<br>(N = 447) | Placebo<br>(N = 455) | Risk Difference for<br>NIC .15 over Placebo |
|--------------------------------------------------|----------------------|----------------------|---------------------------------------------|
| Hyperglycaemia/new onset diabetes mellitus (SMQ) | 121 (27.1)           | 100 (22.0)           | 5.1 (-0.5, 10.7)                            |
| Hyperglycaemia                                   | 114 (25.5)           | 96 (21.1)            | 4.4 (-1.1, 9.9)                             |
| *Coma                                            | 14 (3.1)             | 7 (1.5)              | 1.6 (-0.4, 3.6)                             |
| Polyuria                                         | 2 (0.4)              | 0 (0.0)              | 0.4 (-0.2, 1.1)                             |
| *Hypoglycaemia                                   | 1 (0.2)              | 1 (0.2)              | 0.0 (-0.6, 0.6)                             |
| Acidosis                                         | 0 (0.0)              | 2 (0.4)              | -0.4 (-1.0, 0.2)                            |
| Hypoglycaemia (SMQ)                              | 36 (8.1)             | 22 (4.8)             | 3.2 (0.0, 6.4)                              |
| Agitation                                        | 10 (2.2)             | 0 (0.0)              | 2.2 (0.9, 3.6)                              |
| *Coma                                            | 14 (3.1)             | 7 (1.5)              | 1.6 (-0.4, 3.6)                             |
| Disorientation                                   | 8 (1.8)              | 3 (0.7)              | 1.1 (-0.3, 2.6)                             |
| Lethargy                                         | 6 (1.3)              | 6 (1.3)              | 0.0 (-1.5, 1.5)                             |
| *Hypoglycaemia                                   | 1 (0.2)              | 1 (0.2)              | 0.0 (-0.6, 0.6)                             |
| Diplopia                                         | 0 (0.0)              | 1 (0.2)              | -0.2 (-0.6, 0.2)                            |
| Hyperhidrosis                                    | 0 (0.0)              | 1 (0.2)              | -0.2 (-0.6, 0.2)                            |
| Stupor                                           | 1 (0.2)              | 3 (0.7)              | -0.4 (-1.3, 0.4)                            |
| Hypersensitivity (SMQ)                           | 104 (23.3)           | 106 (23.3)           | -0.0 (-5.5, 5.5)                            |
| Type III immune complex mediated reaction        | 5 (1.1)              | 3 (0.7)              | 0.5 (-0.8, 1.7)                             |
| Choking                                          | 1 (0.2)              | 0 (0.0)              | 0.2 (-0.2, 0.7)                             |
| Laryngeal oedema                                 | 1 (0.2)              | 1 (0.2)              | 0.0 (-0.6, 0.6)                             |
| Urticaria vesiculosa                             | 1 (0.2)              | 1 (0.2)              | 0.0 (-0.6, 0.6)                             |
| Alveolitis                                       | 96 (21.5)            | 102 (22.4)           | -0.9 (-6.3, 4.5)                            |

## ALGORITHMIC MEDICAL QUERIES

In addition to releasing the OCMQs, the FDA also released algorithms for some of the queries. These include seven queries that are limited to biological males or biological females, as well as hyperglycemia, hypersensitivity, hypoglycemia, and muscle injury. The last four queries use a combination of adverse events, laboratory findings, and concomitant medications to identify potential candidates for the medical query.

JMP Clinical applies the algorithms from the OCMQs in the Algorithmic OCMQ Risk Report. The report produces plots with the percent occurrence and risk difference for each algorithmic query as well as tables showing the query and which criteria was met to qualify for the query. The report by default displays the sex specific queries in separate plots and tables from the other queries.

| Medical Query                                                                                                             | NIC .15<br>(N = 11) | Placebo<br>(N = 9) | Risk Difference for<br>NIC .15 over Placebo |
|---------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|---------------------------------------------|
| Hyperglycemia                                                                                                             | 6 (54.5)            | 5 (55.6)           | -1.0 (-44.8, 42.8)                          |
| Any PT from Hyperglycemia OCMQ Narrow                                                                                     | 6 (54.5)            | 1 (11.1)           | 43.4 (7.6, 79.3)                            |
| Fasting Plasma Glucose ≥126 mg/dL                                                                                         | 2 (18.2)            | 0 (0.0)            | 15.8 (-7.0, 38.6)                           |
| ≥2 Plasma Glucoses >180 mg/dL                                                                                             | 1 (9.1)             | 0 (0.0)            | 7.5 (-9.5, 24.5)                            |
| Change from Baseline Fasting Plasma Glucose ≥20 mg/dL with Post Baseline FPG >100 mg/dL                                   | 1 (9.1)             | 0 (0.0)            | 7.5 (-9.5, 24.5)                            |
| Any New Diabetes Concomitant Medication                                                                                   | 0 (0.0)             | 2 (22.2)           | -20.8 (-48.0, 6.3)                          |
| HbA1c Increase ≥0.3% with Post Baseline HbA1c ≥5.7%                                                                       | 0 (0.0)             | 2 (22.2)           | -20.8 (-48.0, 6.3)                          |
| Post Baseline HbA1c ≥6.5%                                                                                                 | 0 (0.0)             | 2 (22.2)           | -20.8 (-48.0, 6.3)                          |
| Hypersensitivity                                                                                                          | 1 (9.1)             | 1 (11.1)           | -2.0 (-28.7, 24.6)                          |
| Angioedema/Topical Reactions and Systemic Reactions within 7 days                                                         | 1 (9.1)             | 1 (11.1)           | -2.0 (-28.7, 24.6)                          |
| Non-algorithmic Narrow PTs                                                                                                | 1 (9.1)             | 1 (11.1)           | -2.0 (-28.7, 24.6)                          |
| Upper Airway/Respiratory and Angioedema/Topical Reactions within 7 days                                                   | 0 (0.0)             | 1 (11.1)           | -10.8 (-31.4, 9.7)                          |
| Upper Airway/Respiratory and Systemic Reactions within 7 days                                                             | 0 (0.0)             | 1 (11.1)           | -10.8 (-31.4, 9.7)                          |
| Hypoglycemia                                                                                                              | 2 (18.2)            | 2 (22.2)           | -4.0 (-39.5, 31.4)                          |
| Plasma Glucose <54 mg/dL                                                                                                  | 1 (9.1)             | 0 (0.0)            | 7.5 (-9.5, 24.5)                            |
| Any Hypoglycemia OCMQ Narrow Term                                                                                         | 1 (9.1)             | 1 (11.1)           | -2.0 (-28.7, 24.6)                          |
| [≥2 Occurrences of a Hypoglycemia OCMQ Broad Term OR Supplemental Term] PLUS [≥2 Occurrences of Plasma Glucose <70 mg/dL] | 0 (0.0)             | 1 (11.1)           | -10.8 (-31.4, 9.7)                          |
| [Any Hypoglycemia OCMQ Broad Term OR Supplemental Term] PLUS [Plasma Glucose <70 mg/dL] with start date within 1 week     | 0 (0.0)             | 2 (22.2)           | -20.8 (-48.0, 6.3)                          |
| Muscle Injury                                                                                                             | 1 (9.1)             | 3 (33.3)           | -24.2 (-59.4, 10.9)                         |
| Any Muscle Injury OCMQ Narrow term                                                                                        | 1 (9.1)             | 1 (11.1)           | -2.0 (-28.7, 24.6)                          |
| CPK >5 x ULN AND NO (CPK-MB/CPK >0.05 with start date within 3 days OR CPK >ULN at baseline)                              | 0 (0.0)             | 1 (11.1)           | -10.8 (-31.4, 9.7)                          |
| Urine myoglobin >ULN                                                                                                      | 0 (0.0)             | 1 (11.1)           | -10.8 (-31.4, 9.7)                          |
| [PT Myalgia + PT Muscular Weakness + (PT Myoglobin Urine Present OR PT Chromaturia)] with start date within 7 days        | 0 (0.0)             | 2 (22.2)           | -20.8 (-48.0, 6.3)                          |

## CONCLUSION

By grouping together adverse events, medical queries provide a standardized way to assess safety signals. The algorithmic OCMQs take this a step further by incorporating indicators of a medical condition from laboratory findings and concomitant medications. JMP Clinical simplifies the analysis of the queries by automating the integration of the medical query files with study data and generating output guided by the FDA Standard Safety Tables and Figures. In the JMP Clinical reports, the data can be further explored through interactive features such as filtering, dynamic options, hover labels, and drilldowns to find potential safety signals.

## REFERENCES

1. U.S. Food and Drug Administration and Duke Margolis Center for Health Policy (2022). Advanced Premarket Safety Analytics Workshop. Retrieved from: <https://healthpolicy.duke.edu/sites/default/files/2022-09/Advancing%20Premarket%20Safety%20Analytics%20Final%20Slide%20Deck.pdf>
2. Office of New Drugs Custom Medical Queries: <https://www.fda.gov/drugs/development-resources/office-new-drugs-custom-medical-queries-ocmqs>
3. FDA Standard Safety Tables and Figures: <https://www.fda.gov/drugs/development-resources/standard-safety-tables-and-figures-stfs>
4. MedDRA Standardised Medical Queries: <https://www.meddra.org/how-to-use/tools/smq>

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