

Comparing Medical Queries with Interactive Graphics

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Introduction

- Types of medical queries
- FDA Standard Tables and Figures
- Medical query specific figures and tables
- Interactive features
- Algorithmic OCMQs

Medical Queries

- Medical queries are groupings of adverse events into medical conditions
- Standardised MedDRA Queries (SMQs)
 - ASCII files downloaded through MedDRA
 - smq_list.asc, smq_content.asc, pt.asc, llt.asc
- Office of New Drugs Custom Medical Queries (OCMQs)
 - Excel file downloaded through FDA website (<https://www.fda.gov/drugs/development-resources/office-new-drugs-custom-medical-queries-ocmqs>)
 - OCMQ Comments and Consolidated List tabs
- Custom Medical Queries
 - Sponsor defined queries in ADAE

FDA Standard Tables and Figures

- Interactive tables and figures guided by FDA Standard Tables and Figures
- Forest plots with frequency and risk difference
- Tables with counts, percents, and risk difference



STANDARD SAFETY TABLES AND FIGURES: *INTEGRATED GUIDE*

Center for Drug Evaluation and Research (CDER)

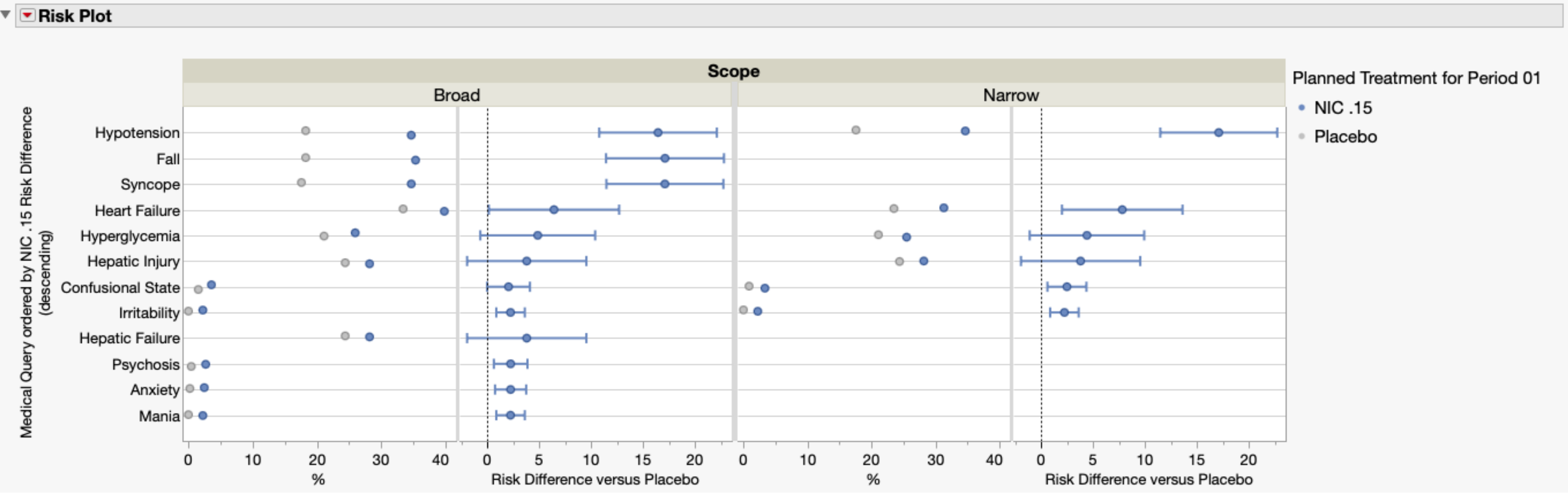
Biomedical Informatics and Regulatory Review Science (BIRRS) Team

Please email ONDbiomedicalInformatics@fda.hhs.gov with any questions.

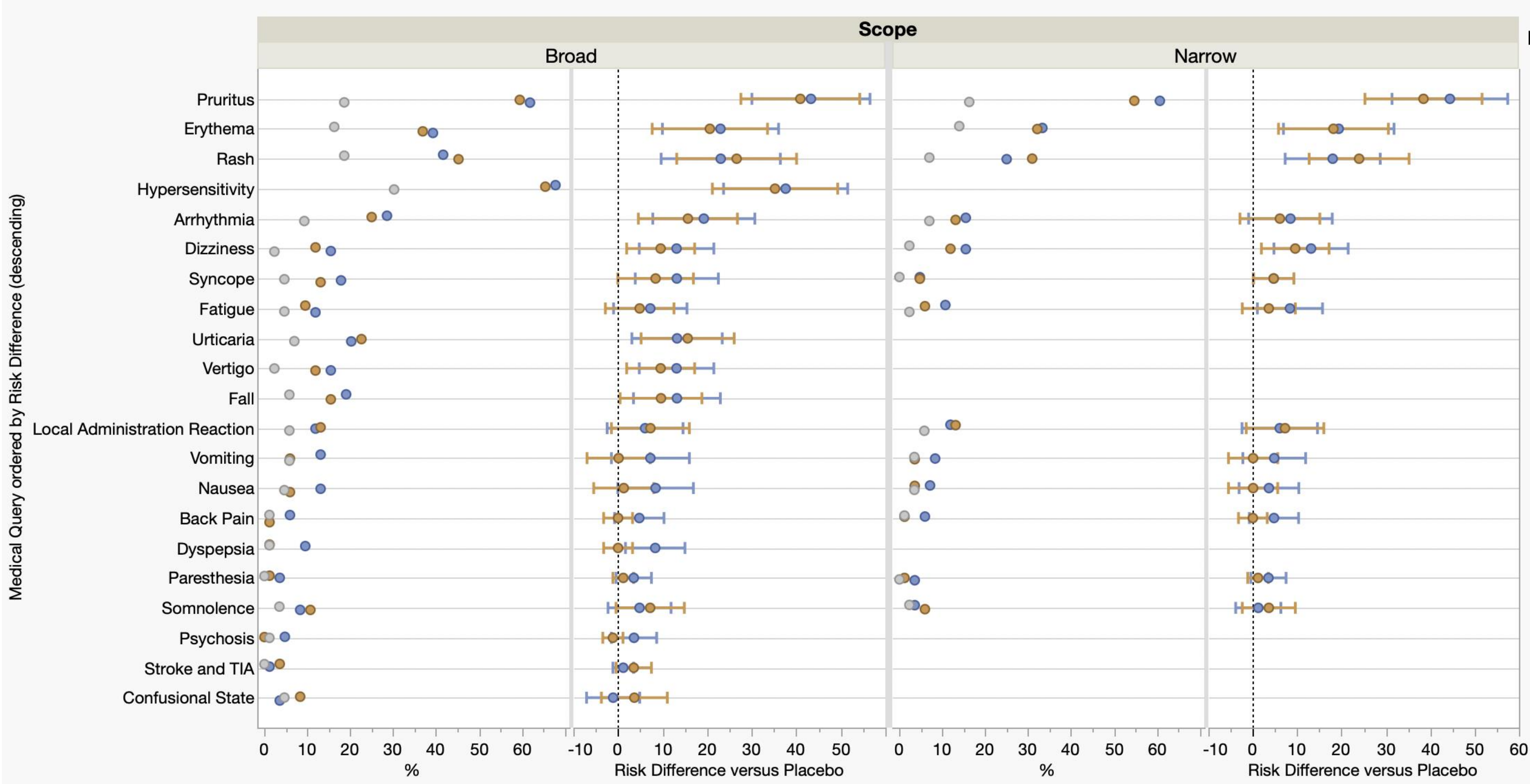
Version Number: 2.0

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Forest Plots



Forest Plots with Multiple Active Treatment Groups



Narrow Medical Queries and Terms Table

Narrow Medical Queries and Terms			
Medical Query	NIC .15 (N = 447)	Placebo (N = 455)	Risk Difference for 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)

Broad Medical Queries and Terms Table

Broad Medical Queries and Terms			
Medical Query	NIC .15 (N = 447)	Placebo (N = 455)	Risk Difference for NIC .15 over Placebo
Fall	158 (35.3)	83 (18.2)	17.1 (11.4, 22.8)
*Hypotension	155 (34.7)	80 (17.6)	17.1 (11.5, 22.7)
Dizziness exertional	7 (1.6)	4 (0.9)	0.7 (-0.7, 2.1)
Syncope	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)
*Hypotension	155 (34.7)	83 (18.2)	16.4 (10.8, 22.1)
*Hypotension	155 (34.7)	80 (17.6)	17.1 (11.5, 22.7)
Hypovolaemia	0 (0.0)	3 (0.7)	-0.7 (-1.4, 0.1)
Heart Failure	178 (39.8)	152 (33.4)	6.4 (0.1, 12.7)
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)
Oedema peripheral	94 (21.0)	91 (20.0)	1.0 (-4.2, 6.3)
Dyspnoea	2 (0.4)	0 (0.0)	0.4 (-0.2, 1.1)
Cardiomegaly	0 (0.0)	2 (0.4)	-0.4 (-1.0, 0.2)
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)
Hepatic Failure	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)
*Ascites	1 (0.2)	0 (0.0)	0.2 (-0.2, 0.7)
*Hyperbilirubinaemia	0 (0.0)	1 (0.2)	-0.2 (-0.6, 0.2)
*Jaundice	0 (0.0)	1 (0.2)	-0.2 (-0.6, 0.2)
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)
*Ascites	1 (0.2)	0 (0.0)	0.2 (-0.2, 0.7)
Hepatomegaly	1 (0.2)	0 (0.0)	0.2 (-0.2, 0.7)
*Hyperbilirubinaemia	0 (0.0)	1 (0.2)	-0.2 (-0.6, 0.2)
*Jaundice	0 (0.0)	1 (0.2)	-0.2 (-0.6, 0.2)

*Terms in Multiple Medical Query

Medical Query and Dictionary-Derived Term	Scope
Ascites	
<i>Hepatic Failure</i>	Broad
<i>Hepatic Injury</i>	Broad
Hepatic function abnormal	
<i>Hepatic Failure</i>	Broad
<i>Hepatic Injury</i>	Broad
Hyperbilirubinaemia	
<i>Hepatic Failure</i>	Broad
<i>Hepatic Injury</i>	Broad
Hypotension	
<i>Fall</i>	Broad
<i>Syncope</i>	Broad
<i>Hypotension</i>	Broad
Jaundice	
<i>Hepatic Failure</i>	Broad
<i>Hepatic Injury</i>	Broad

Overall Medical Query Table

Medical Query	Scope	NIC .15 (N = 447)	Placebo (N = 455)	Risk Difference for NIC .15 over Placebo
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)

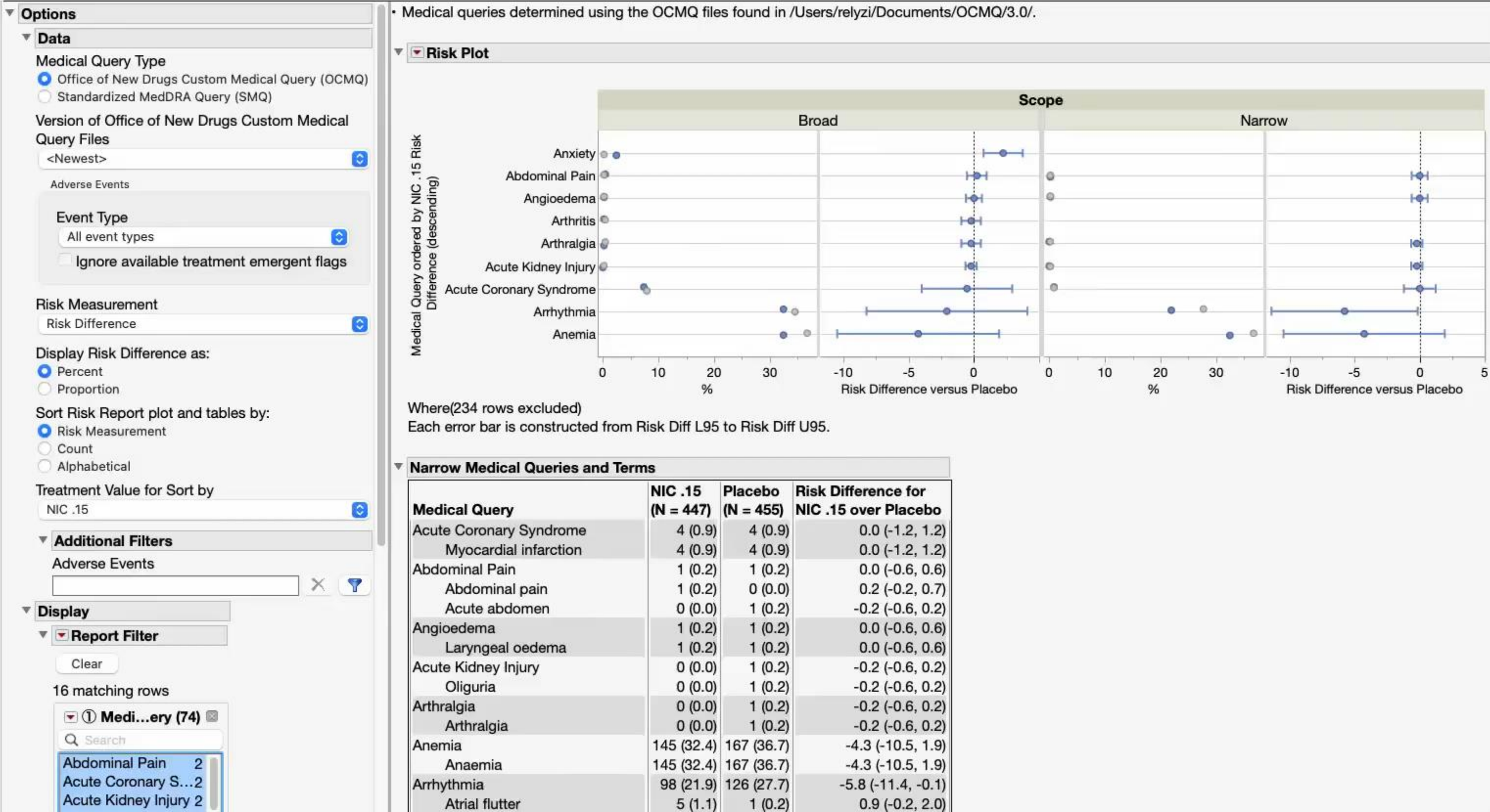
Medical Query and System Organ Class Table

System Organ Class				
System Organ Class	Scope	NIC .15 (N = 447)	Placebo (N = 455)	Risk Difference for NIC .15 over Placebo
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)

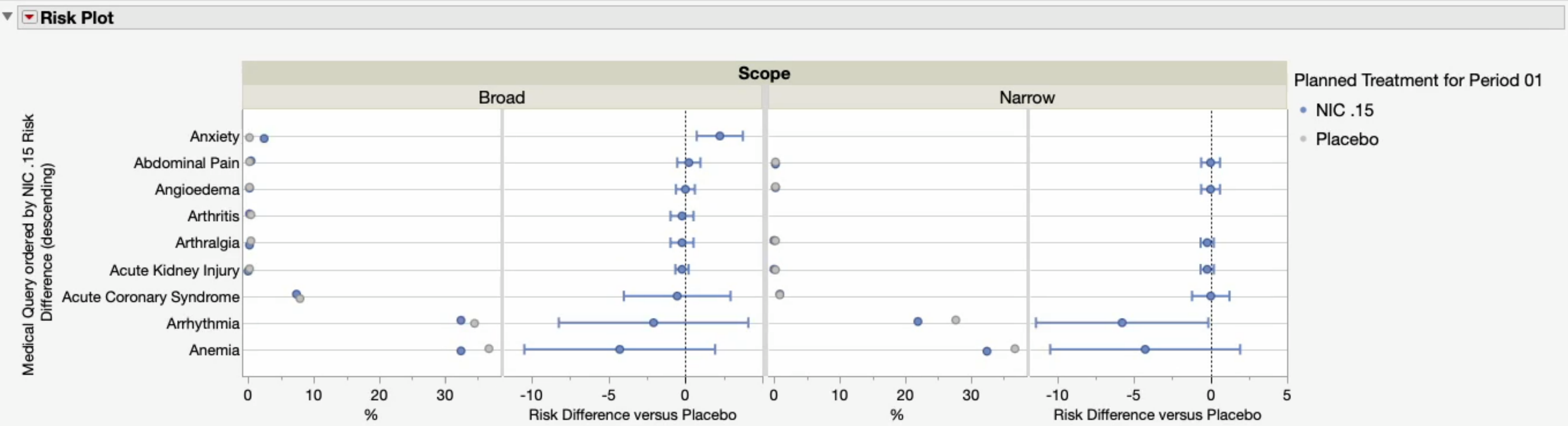
Filtering



Dynamic Options



Hover Labels



Listings of Patients with Specific Medical Queries

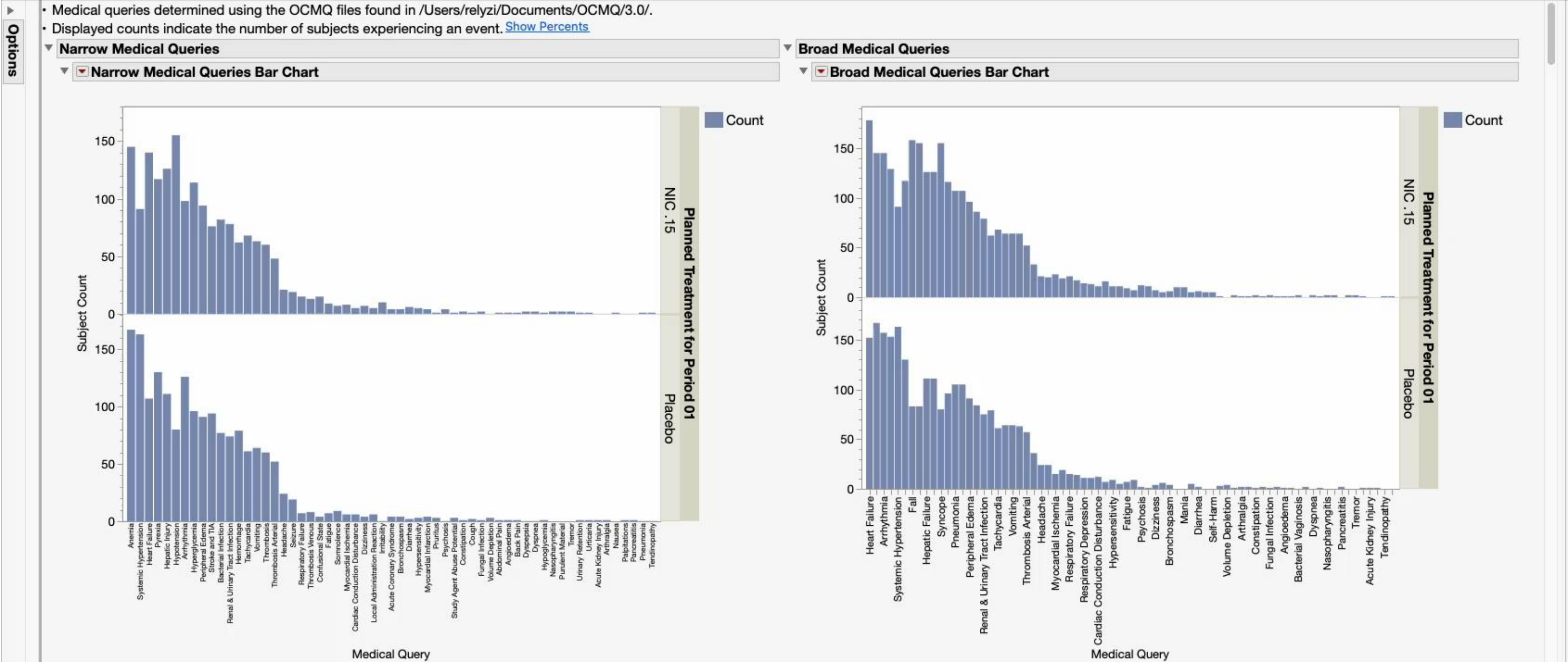
▼ Narrow Medical Queries and Terms

Medical Query	NIC .15 (N = 447)	Placebo (N = 455)	Risk Difference for NIC .15 over Placebo
Acute Coronary Syndrome	4 (0.9)	4 (0.9)	0.0 (-1.2, 1.2)
Myocardial infarction	4 (0.9)	4 (0.9)	0.0 (-1.2, 1.2)
Abdominal Pain	1 (0.2)	1 (0.2)	0.0 (-0.6, 0.6)
Abdominal pain	1 (0.2)	0 (0.0)	0.2 (-0.2, 0.7)
Acute abdomen	0 (0.0)	1 (0.2)	-0.2 (-0.6, 0.2)
Arrhythmia	98 (21.9)	126 (27.7)	-5.8 (-11.4, -0.1)
Atrial flutter	5 (1.1)	1 (0.2)	0.9 (-0.2, 2.0)
Supraventricular extrasystoles	25 (5.6)	22 (4.8)	0.8 (-2.1, 3.7)
Supraventricular tachycardia	10 (2.2)	7 (1.5)	0.7 (-1.1, 2.5)
Atrial fibrillation	18 (4.0)	17 (3.7)	0.3 (-2.2, 2.8)
Ventricular fibrillation	2 (0.4)	1 (0.2)	0.2 (-0.5, 1.0)
Ventricular tachycardia	3 (0.7)	3 (0.7)	0.0 (-1.0, 1.1)
Ventricular extrasystoles	42 (9.4)	43 (9.5)	-0.1 (-3.9, 3.8)
Arrhythmia	0 (0.0)	1 (0.2)	-0.2 (-0.6, 0.2)
Ventricular arrhythmia	0 (0.0)	1 (0.2)	-0.2 (-0.6, 0.2)
Withdrawal arrhythmia	0 (0.0)	1 (0.2)	-0.2 (-0.6, 0.2)
Bradycardia	0 (0.0)	2 (0.4)	-0.4 (-1.0, 0.2)
Sinus bradycardia	20 (4.5)	47 (10.3)	-5.9 (-9.2, -2.5)

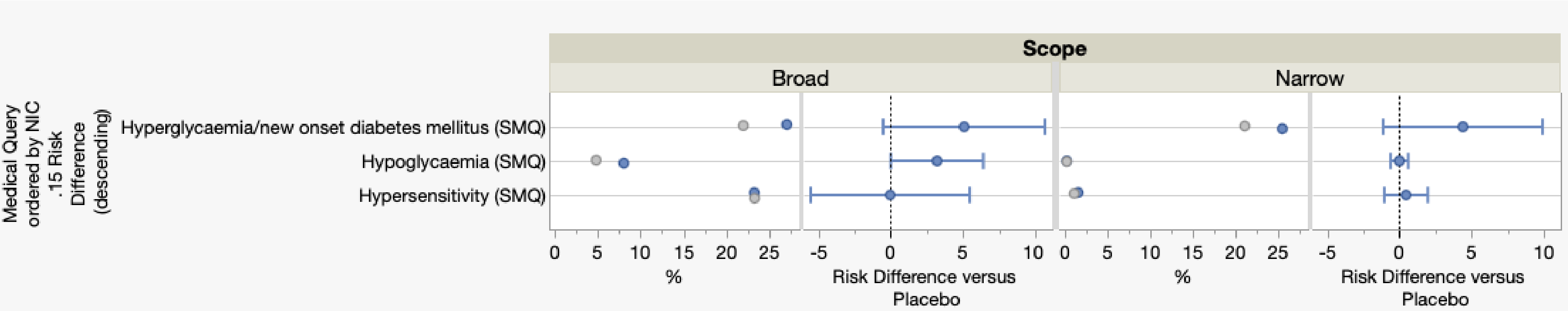
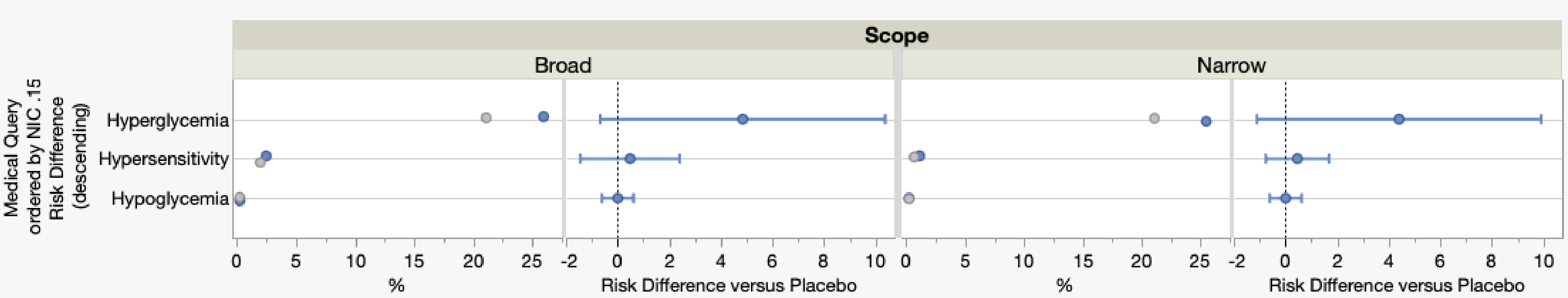
▼ Broad Medical Queries and Terms

Medical Query	NIC .15 (N = 447)	Placebo (N = 455)	Risk Difference for NIC .15 over Placebo
Abdominal Pain	2 (0.4)	1 (0.2)	0.2 (-0.5, 1.0)
Abdominal pain	1 (0.2)	0 (0.0)	0.2 (-0.2, 0.7)
Peptic ulcer	1 (0.2)	0 (0.0)	0.2 (-0.2, 0.7)
Acute abdomen	0 (0.0)	1 (0.2)	-0.2 (-0.6, 0.2)
Acute Coronary Syndrome	33 (7.4)	36 (7.9)	-0.5 (-4.0, 2.9)
Myocardial ischaemia	3 (0.7)	2 (0.4)	0.2 (-0.7, 1.2)
Angina pectoris	1 (0.2)	0 (0.0)	0.2 (-0.2, 0.7)
Cardiac arrest	7 (1.6)	7 (1.5)	0.0 (-1.6, 1.6)
Myocardial infarction	4 (0.9)	4 (0.9)	0.0 (-1.2, 1.2)
Blood creatine phosphokinase increased	20 (4.5)	24 (5.3)	-0.8 (-3.6, 2.0)
Arrhythmia	145 (32.4)	157 (34.5)	-2.1 (-8.2, 4.1)

Alternative view - Distributions



Comparing OCMQs and SMQs



Comparing OCMQs and SMQs

Broad Medical Queries and Terms			
Medical Query	NIC .15 (N = 447)	Placebo (N = 455)	Risk Difference for 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 (N = 447)	Placebo (N = 455)	Risk Difference for 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 OCMQs

Sex Specific Algorithms

- Seven OCMQs limited to biological males or females
- Abnormal Uterine Bleeding, Amenorrhea, Bacterial Vaginosis, Decreased Menstrual Bleeding, Erectile Dysfunction, Excessive Menstrual Bleeding, Gynecomastia

Other Algorithms

- Hyperglycemia, Hypersensitivity, Hypoglycemia, Muscle Injury
- Use adverse events, laboratory findings, and concomitant medications

Algorithmic OCMQ Tables

Medical Query	NIC .15 (N = 11)	Placebo (N = 9)	Risk Difference for 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 $\geq 0.3\%$ with Post Baseline HbA1c $\geq 5.7\%$	0 (0.0)	2 (22.2)	-20.8 (-48.0, 6.3)
Post Baseline HbA1c $\geq 6.5\%$	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)
$[\geq 2$ Occurrences of a Hypoglycemia OCMQ Broad Term OR Supplemental Term] PLUS $[\geq 2$ 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 $> 5 \times$ ULN AND NO (CPK-MB/CPK > 0.05 with start date within 3 days OR CPK $> \text{ULN}$ at baseline)	0 (0.0)	1 (11.1)	-10.8 (-31.4, 9.7)
Urine myoglobin $> \text{ULN}$	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)

Resources

- Office of New Drugs Custom Medical Queries
<https://www.fda.gov/drugs/development-resources/office-new-drugs-custom-medical-queries-ocmqs>
- FDA Standard Safety Tables and Figures
<https://www.fda.gov/drugs/development-resources/standard-safety-tables-and-figures-stfs>
- MedDRA Standardised Medical Queries
<https://www.meddra.org/how-to-use/tools/smqqs>

Resources

[Home](#) > [Drug Safety](#) > [Article](#)

Aggregation of Adverse Event Terms for Signal Detection and Labeling in Clinical Trials

Leading Article | Published: 14 February 2025

Volume 48, pages 595–606, (2025) [Cite this article](#)



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[Richard C. Zink](#) , [Rebecca Lyzinski](#) & [Geoffrey Mann](#)

Access

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Thank you!

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