

Comparing Medical Queries with Interactive Graphics using JMP Clinical

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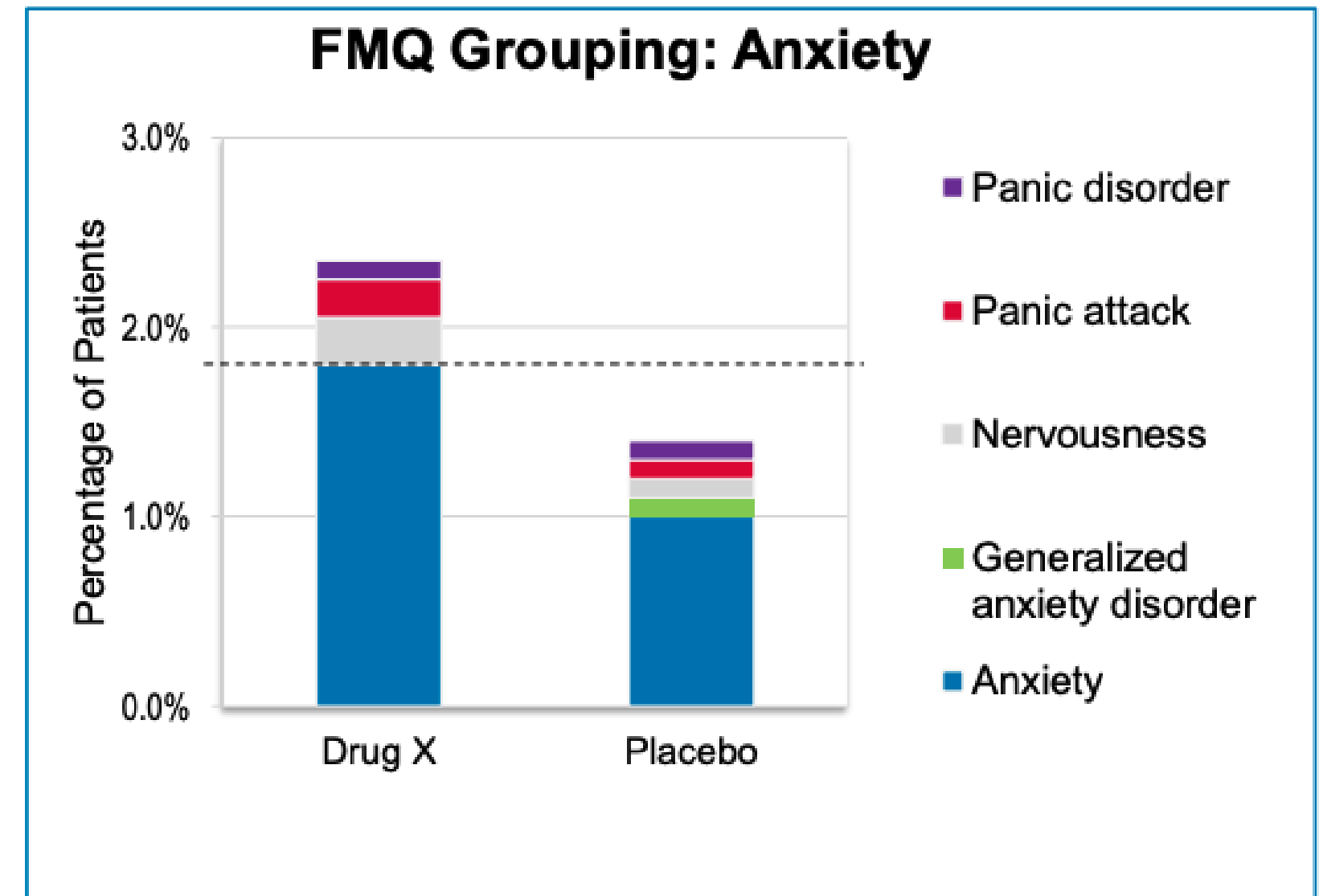


Introduction

- Introduction to medical queries
- Types of medical queries
- Format of medical queries and merging with study data
- FDA Standard Tables and Figures
- Medical query specific figures and tables
- JMP Clinical reports and interactive features
- Algorithmic OCMQs

Medical Queries

- Medical queries are groupings of adverse events into medical conditions
- Provides a standard way to assist with identifying safety issues
- Narrow medical queries
 - Specific terms that provide high probability the condition occurred
- Broad medical queries
 - Less specific
 - Provides reasonable assurance the condition occurred



([Advanced Premarket Safety Analytics Workshop](#), 2022)

Types of Medical Queries

- 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

Standardised MedDRA Queries

- Merge smq_list and smq_content by SMQ Code

	SMQ_code	SMQ_name
1	20000001	Torsade de pointes/QT prolongation (SMQ)
2	20000002	Rhabdomyolysis/myopathy (SMQ)
3	20000003	Acute renal failure (SMQ)
4	20000004	Cardiac failure (SMQ)
5	20000005	Hepatic disorders (SMQ)
6	20000006	Drug related hepatic disorders - comprehensive search (SMQ)
7	20000007	Drug related hepatic disorders - severe events only (SMQ)
8	20000008	Liver related investigations, signs and symptoms (SMQ)
9	20000009	Cholestasis and jaundice of hepatic origin (SMQ)
10	20000010	Hepatitis, non-infectious (SMQ)
11	20000011	Liver neoplasms, malignant and unspecified (SMQ)
12	20000012	Liver neoplasms, benign (incl cysts and polyps) (SMQ)
13	20000013	Hepatic failure, fibrosis and cirrhosis and other liver damage-relat...
14	20000014	Congenital, familial, neonatal and genetic disorders of the liver (S...
15	20000015	Liver-related coagulation and bleeding disturbances (SMQ)
16	20000016	Liver infections (SMQ)
17	20000017	Hepatic disorders specifically reported as alcohol-related (SMQ)
18	20000018	Pregnancy-related hepatic disorders (SMQ)
19	20000019	Haemolytic disorders (SMQ)
20	20000020	Severe cutaneous adverse reactions (SMQ)
21	20000021	Anaphylactic reaction (SMQ)
22	20000022	Acute pancreatitis (SMQ)

	SMQ_code	Term_code	Term_level	Term_scope
1	20000001	10003109	5	1
2	20000001	10003131	5	1
3	20000001	10003132	5	1
4	20000001	10003586	5	1
5	20000001	10003587	5	1
6	20000001	10003589	5	1
7	20000001	10004978	5	1
8	20000001	10004979	5	1
9	20000001	10004980	5	1
10	20000001	10004982	5	1
11	20000001	10004983	5	1
12	20000001	10007515	4	1
13	20000001	10007517	5	1
14	20000001	10007565	5	1
15	20000001	10007617	4	1
16	20000001	10007644	5	1
17	20000001	10010683	5	1
18	20000001	10010766	5	1
19	20000001	10010771	5	1
20	20000001	10010772	5	1
21	20000001	10011915	5	1
22	20000001	10011938	5	1

Standardised MedDRA Queries

- Next merge with pt and llt files as applicable

	 Σ		pt_code	pt_name
	1		10000002	11-beta-hydroxylase deficiency
	2		10000005	17 ketosteroids urine
	3		10000007	17 ketosteroids urine decreased
	4		10000009	17 ketosteroids urine increased
	5		10000011	17 ketosteroids urine normal
	6		10000013	17,20-desmolase deficiency
	7		10000014	17-alpha-hydroxylase deficiency
	8		10000020	20,22-desmolase deficiency
	9		10000021	21-hydroxylase deficiency
	10		10000028	5'nucleotidase increased
	11		10000029	5-alpha-reductase deficiency
	12		10000044	Abdomen crushing
	13		10000050	Abdominal adhesions
	14		10000059	Abdominal discomfort
	15		10000060	Abdominal distension
	16		10000077	Abdominal mass
	17		10000081	Abdominal pain
	18		10000084	Abdominal pain lower
	19		10000087	Abdominal pain upper
	20		10000090	Abdominal rigidity
	21		10000094	Abdominal sinus repair
	22		10000097	Abdominal tenderness

	 Σ		llt_code	llt_name	pt_code
	1		10000001	"Ventilation" pneumonitis	10081988
	2		10000002	11-beta-hydroxylase deficiency	10000002
	3		10000003	11-oxysteroid activity incr	10033315
	4		10000004	11-oxysteroid activity increased	10033315
	5		10000005	17 ketosteroids urine	10000005
	6		10000006	17 ketosteroids urine abnormal NOS	10061608
	7		10000007	17 ketosteroids urine decreased	10000007
	8		10000008	17 ketosteroids urine high	10000009
	9		10000009	17 ketosteroids urine increased	10000009
	10		10000010	17 ketosteroids urine low	10000007
	11		10000011	17 ketosteroids urine normal	10000011
	12		10000012	17 OHCS increased	10020539
	13		10000013	17,20-desmolase deficiency	10000013
	14		10000014	17-alpha-hydroxylase deficiency	10000014
	15		10000015	17-hydroxycorticosteroid activity increased	10021684
	16		10000016	17-hydroxysteroid activity incr	10021684
	17		10000017	17-hydroxysteroid activity increased	10021684
	18		10000018	1st degree heart block	10003674
	19		10000019	1st degree vaginal prolapse	10046940
	20		10000020	20,22-desmolase deficiency	10000020
	21		10000021	21-hydroxylase deficiency	10000021
	22		10000022	2nd degree heart block	10003677

FDA Medical Queries – Consolidated List Tab

OCMQ	Term	OCMQ-Term	Final Classification
Abdominal Pain	Abdominal discomfort	Abdominal Pain-Abdominal discomfort	Narrow
Abdominal Pain	Abdominal migraine	Abdominal Pain-Abdominal migraine	Narrow
Abdominal Pain	Abdominal pain	Abdominal Pain-Abdominal pain	Narrow
Abdominal Pain	Abdominal pain NOS	Abdominal Pain-Abdominal pain NOS	Narrow
Abdominal Pain	Abdominal pain aggravated	Abdominal Pain-Abdominal pain aggravated	Narrow
Abdominal Pain	Abdominal pain lower	Abdominal Pain-Abdominal pain lower	Narrow
Abdominal Pain	Abdominal pain upper	Abdominal Pain-Abdominal pain upper	Narrow
Abdominal Pain	Abdominal rebound tenderness	Abdominal Pain-Abdominal rebound tenderness	Narrow
Abdominal Pain	Abdominal rigidity	Abdominal Pain-Abdominal rigidity	Narrow
Abdominal Pain	Abdominal tenderness	Abdominal Pain-Abdominal tenderness	Narrow
Abdominal Pain	Abdominal wall pain	Abdominal Pain-Abdominal wall pain	Narrow
Abdominal Pain	Acute abdomen	Abdominal Pain-Acute abdomen	Narrow
Abdominal Pain	Appendicitis	Abdominal Pain-Appendicitis	Narrow
Abdominal Pain	Campylobacter test	Abdominal Pain-Campylobacter test	Narrow
Abdominal Pain	Complicated appendicitis	Abdominal Pain-Complicated appendicitis	Narrow
Abdominal Pain	Duodenal rupture	Abdominal Pain-Duodenal rupture	Narrow
Abdominal Pain	Enteric neuropathy	Abdominal Pain-Enteric neuropathy	Narrow
Abdominal Pain	Epigastric discomfort	Abdominal Pain-Epigastric discomfort	Narrow
Abdominal Pain	Gastrointestinal discomfort	Abdominal Pain-Gastrointestinal discomfort	Narrow
Abdominal Pain	Gastrointestinal pain	Abdominal Pain-Gastrointestinal pain	Narrow
Abdominal Pain	Gastrointestinal pain NOS	Abdominal Pain-Gastrointestinal pain NOS	Narrow
Abdominal Pain	Gastrointestinal upset	Abdominal Pain-Gastrointestinal upset	Narrow
Abdominal Pain	Ilioinguinal neuralgia	Abdominal Pain-Ilioinguinal neuralgia	Narrow
Abdominal Pain	Intestinal spasm	Abdominal Pain-Intestinal spasm	Narrow
Abdominal Pain	Intestinal vascular disorder	Abdominal Pain-Intestinal vascular disorder	Narrow
Abdominal Pain	Mesenteric vein embolism	Abdominal Pain-Mesenteric vein embolism	Narrow
Abdominal Pain	Omental torsion	Abdominal Pain-Omental torsion	Narrow
Abdominal Pain	Omentitis	Abdominal Pain-Omentitis	Narrow
Abdominal Pain	Perihepatic discomfort	Abdominal Pain-Perihepatic discomfort	Narrow
Abdominal Pain	Spleen pain	Abdominal Pain-Spleen pain	Narrow
Abdominal Pain	Splenic torsion	Abdominal Pain-Splenic torsion	Narrow
Abdominal Pain	Spontaneous splenic rupture	Abdominal Pain-Spontaneous splenic rupture	Narrow
Abdominal Pain	Stomach discomfort	Abdominal Pain-Stomach discomfort	Narrow

FDA Medical Queries – OCMQ Comments Tab

OCMQ NAME	FIRST PUBLISHED	COMMENT LAST UPDATED	ORGAN SYSTEM	OCMQ COMMENT	ALGORITHM CRITERIA
Abdominal Pain	v1.0	v2.1	Gastrointestinal disorders	The preferred term “Dyspepsia” is not included in this OCMQ as the quality of the sensation of dyspepsia, while unpleasant, is considered insufficiently similar to pain.	No
Abnormal Uterine Bleeding	v1.0	v2.1	Reproductive system and breast disorders	The Abnormal Uterine Bleeding OCMQ excludes structural causes of abnormal uterine bleeding as doing so is consistent with the clinical definition of this term. In addition, because uterine fibroids and polyps are common and do not consistently cause bleeding, including such terms in the OCMQ would impair rather than promote detection of this safety concern. As abnormal uterine bleeding is a condition that only occurs in biological females, all statistical calculations for this OCMQ should be limited to that population.	No
Acute Coronary Syndrome	v1.0	v2.0	Cardiac disorders	Not applicable	No
Acute Kidney Injury	v1.0	v2.0	Renal and urinary disorders	The Acute Kidney Injury (AKI) OCMQ is intended to identify a potential signal for acute onset kidney injury leading to a decrease in kidney function in situations where there was not a prior concern for nephrotoxicity, and therefore the protocol was not designed to detect and characterize this risk by other means. Narrow terms indicate a high likelihood of AKI, while Broad terms indicate only a reasonable possibility of that event. Terms indicating chronic kidney disease or consistent with either acute or chronic disease, such as “Renal failure,” were placed in Broad and excluded from Narrow.	No
Alopecia	v1.0	v2.1	Skin and subcutaneous tissue disorders	For the Alopecia OCMQ, “Hypotrichosis” is included as a Broad term as it refers to having less than a normal amount of hair and not specifically to hair loss. “Trichorrhexis” is included within Broad because it is a hair shaft defect that contributes to hair loss but does not necessarily indicate the presence of hair loss.	No
Amenorrhea	v1.0	v2.1	Reproductive system and breast disorders	As amenorrhea is a condition that only occurs in biological females, all statistical calculations for this OCMQ should be limited to that population.	No

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)

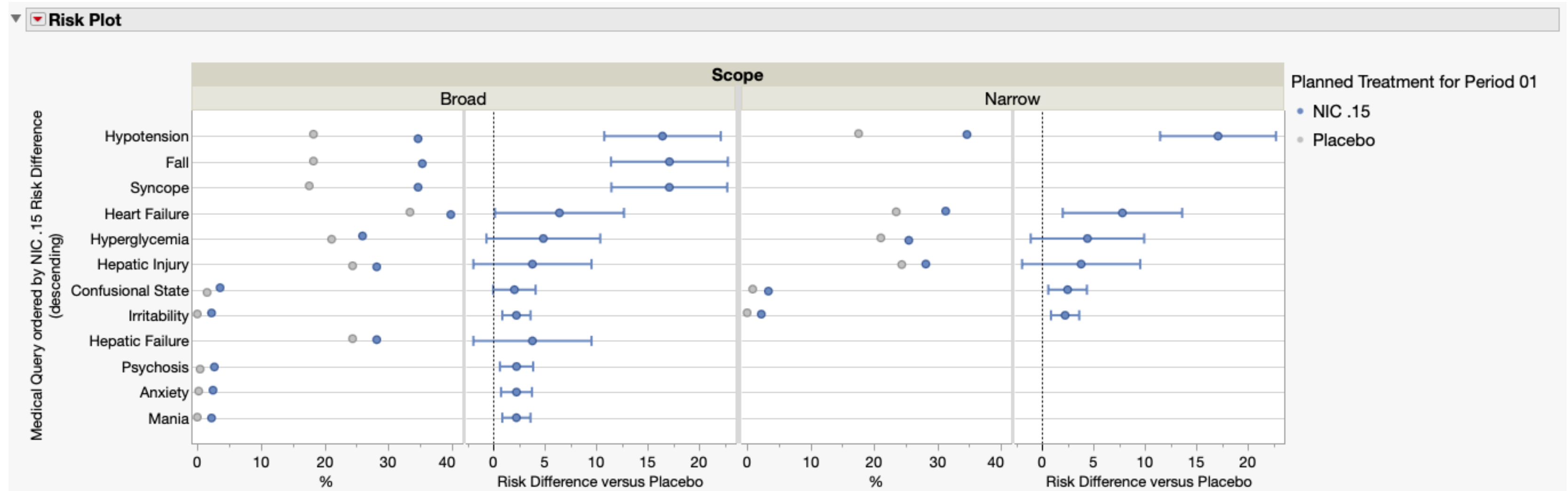
Biomedical Informatics and Regulatory Review Science (BIRRS) Team

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

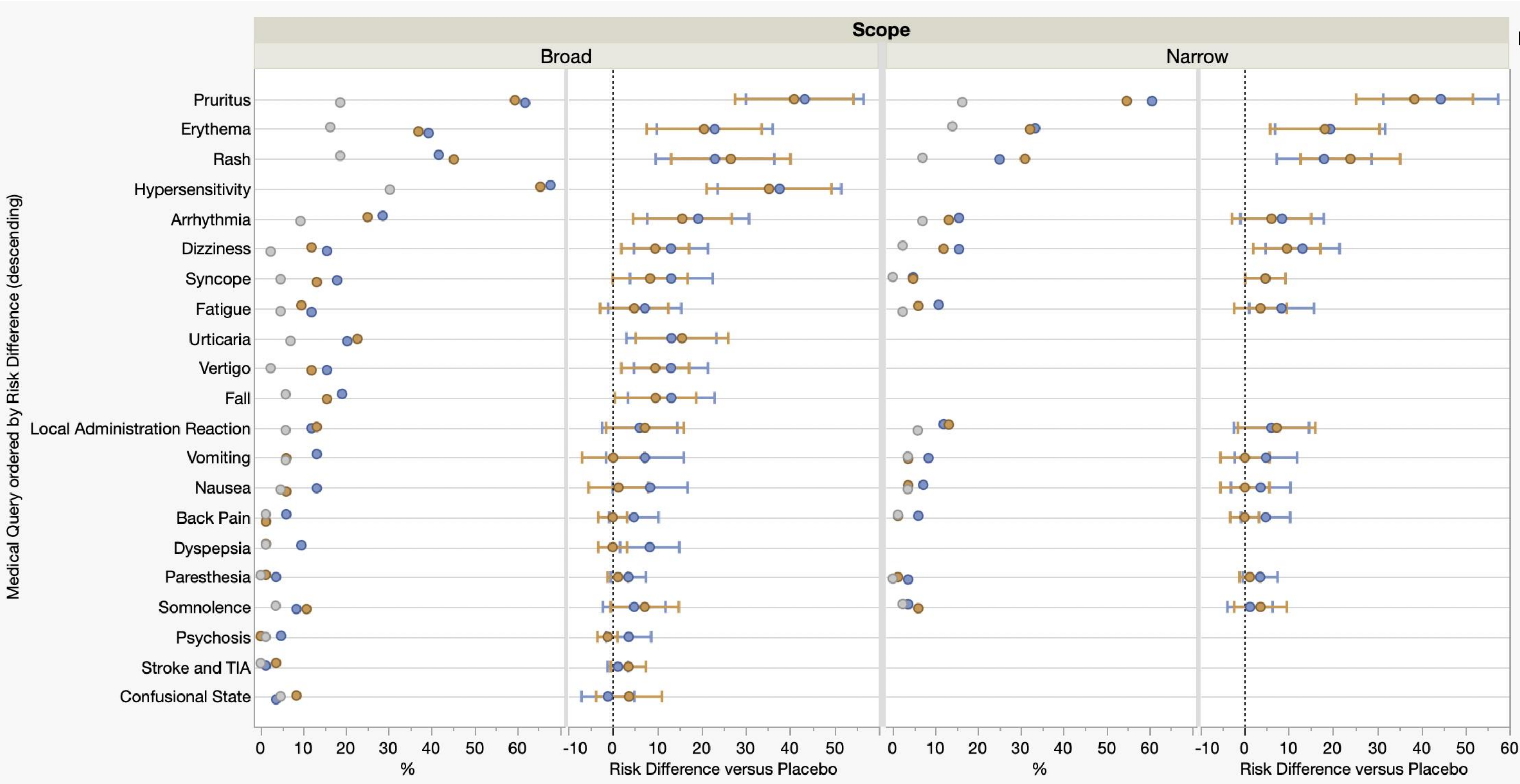
Version Number: 2.0

Version Date: April 2025

Forest Plots: Two Treatment Groups



Forest Plots: 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

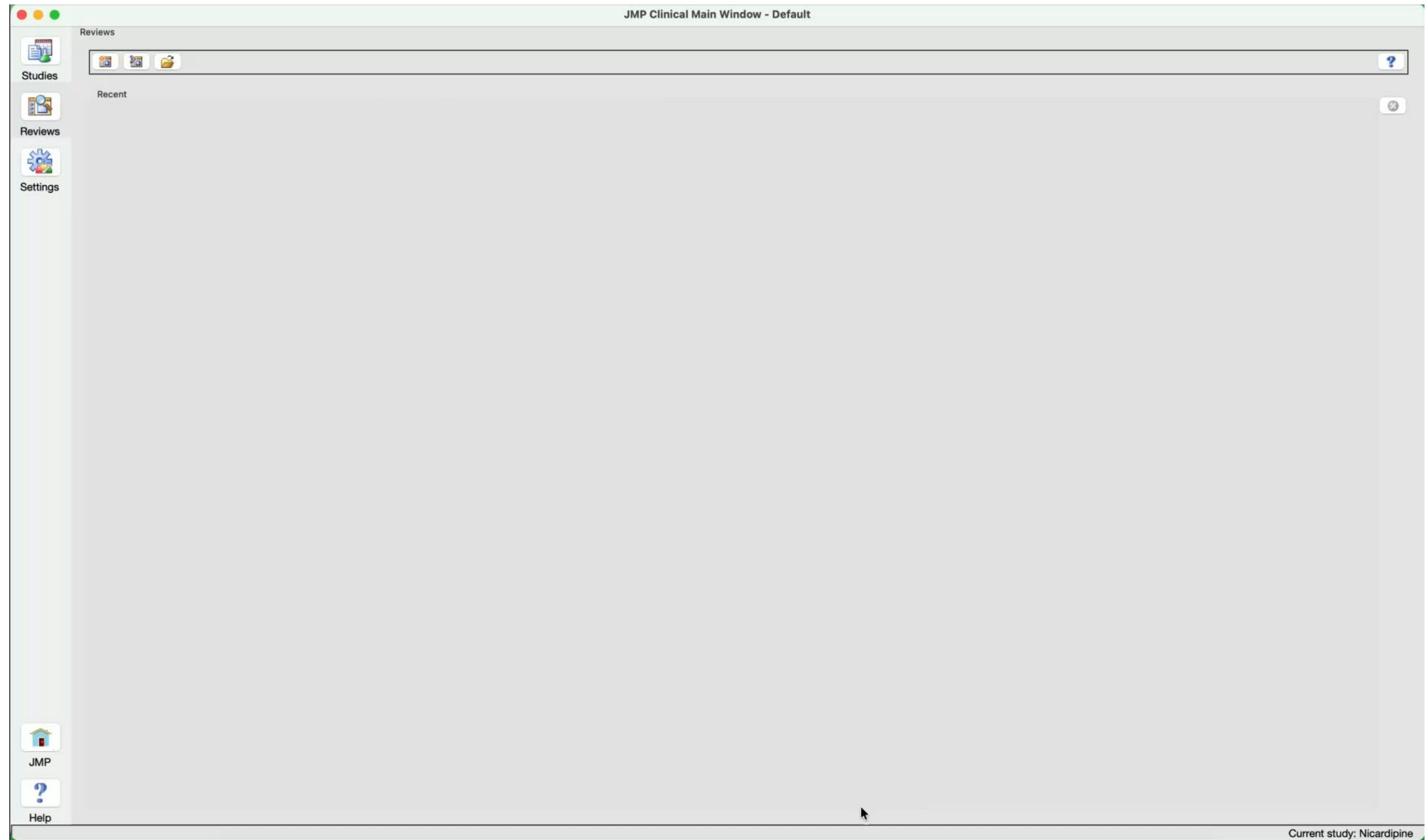
Overall Medical Query Table

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)

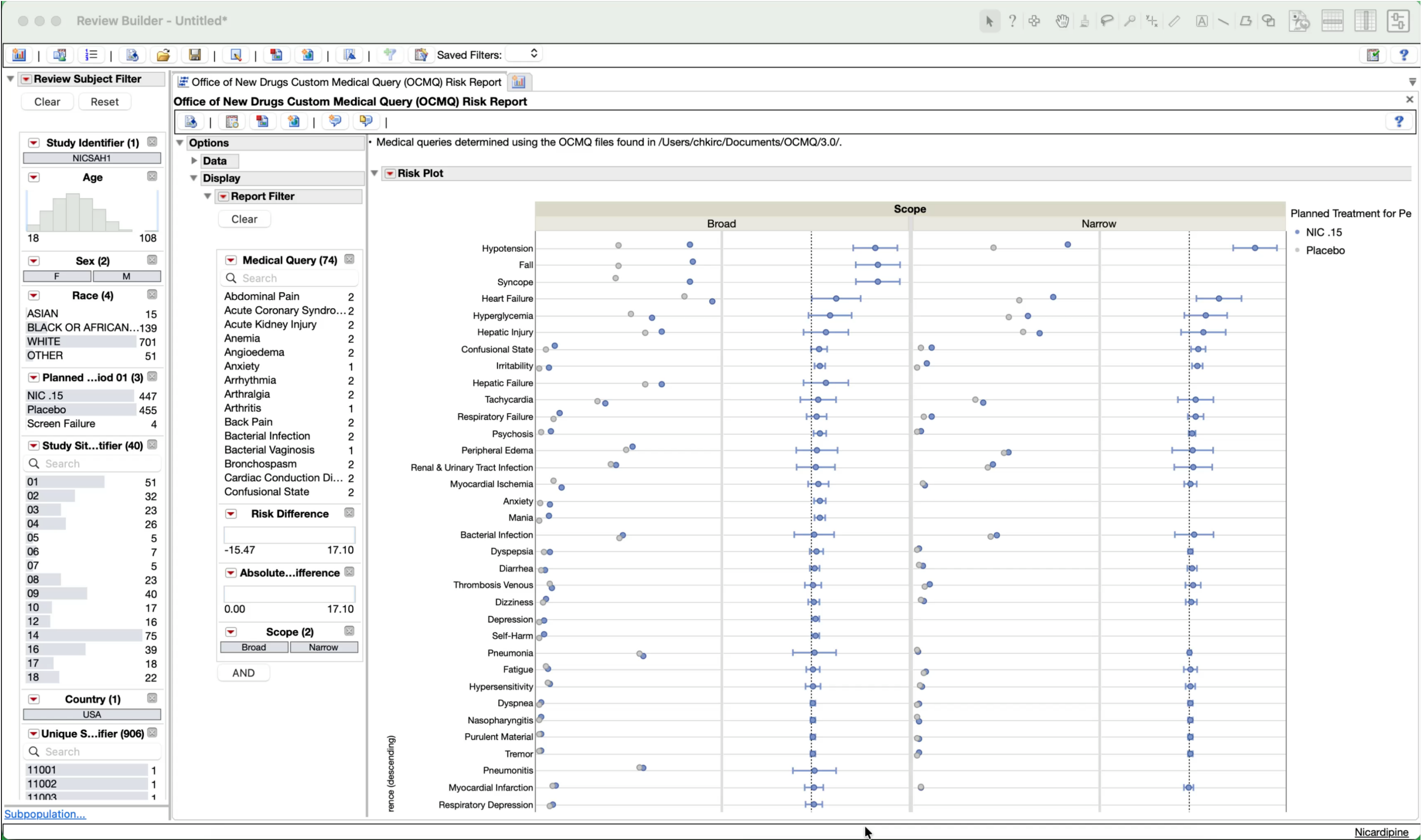
Medical Query and System Organ Class Table

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)

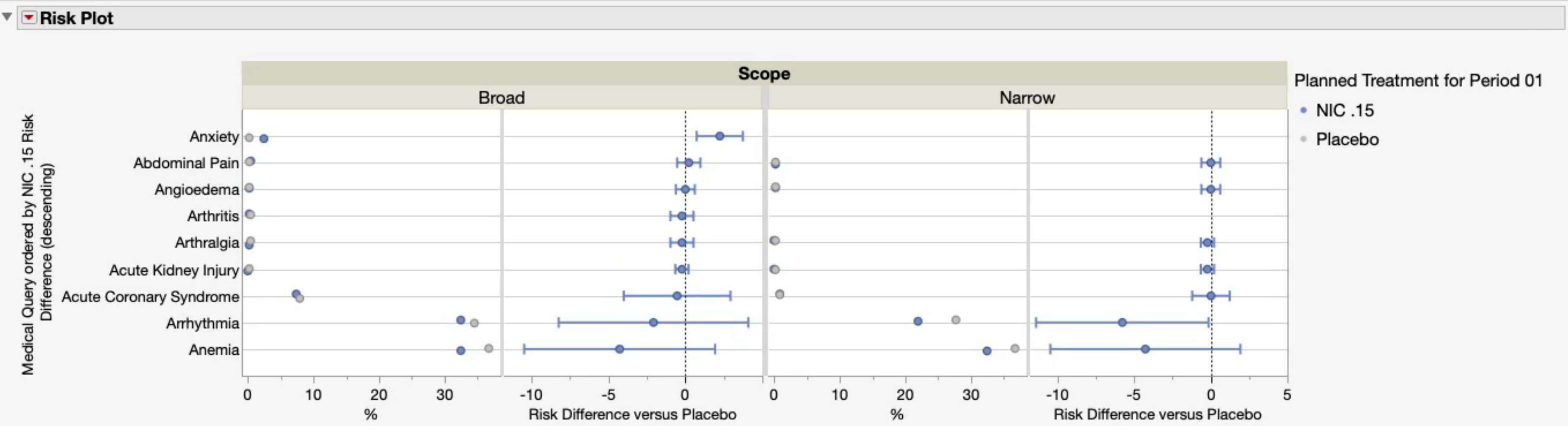
JMP Clinical



Dynamic Options



Hover Labels

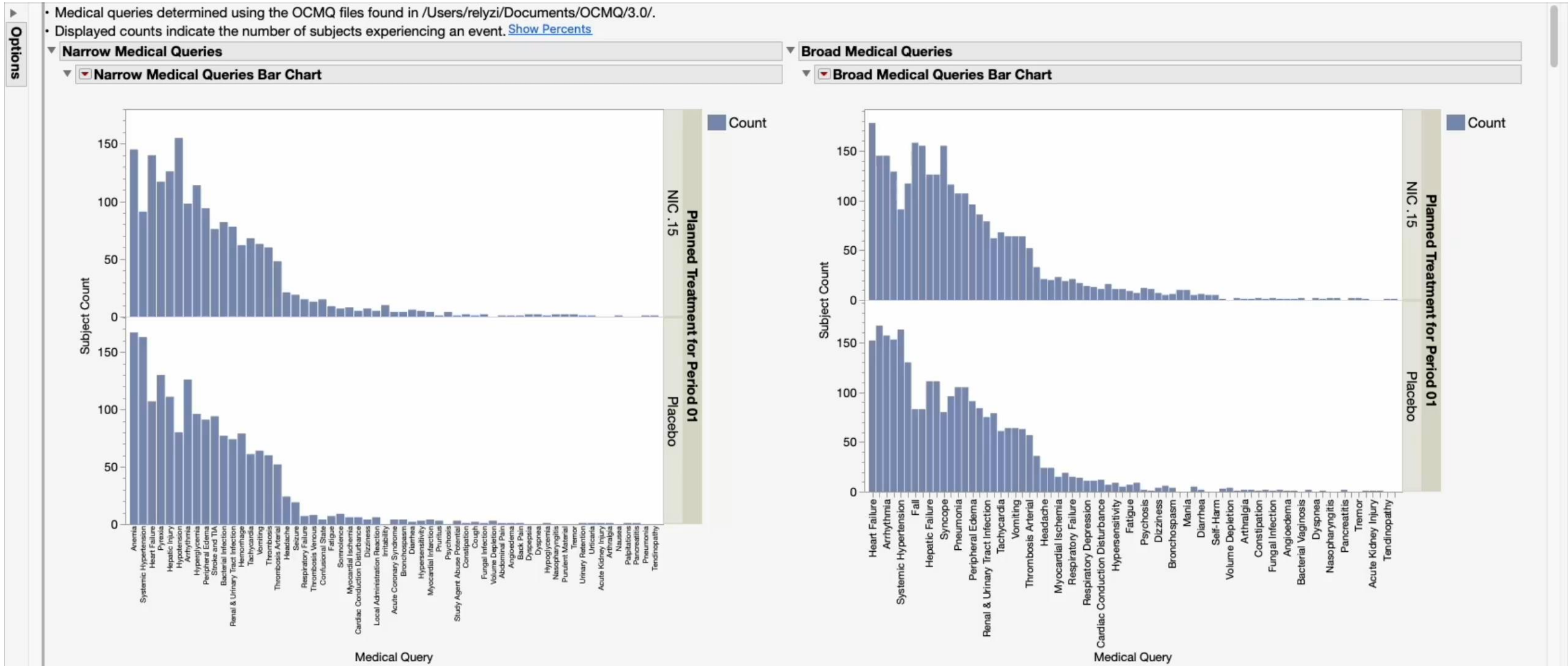


Listings of Patients with Specific Medical Queries

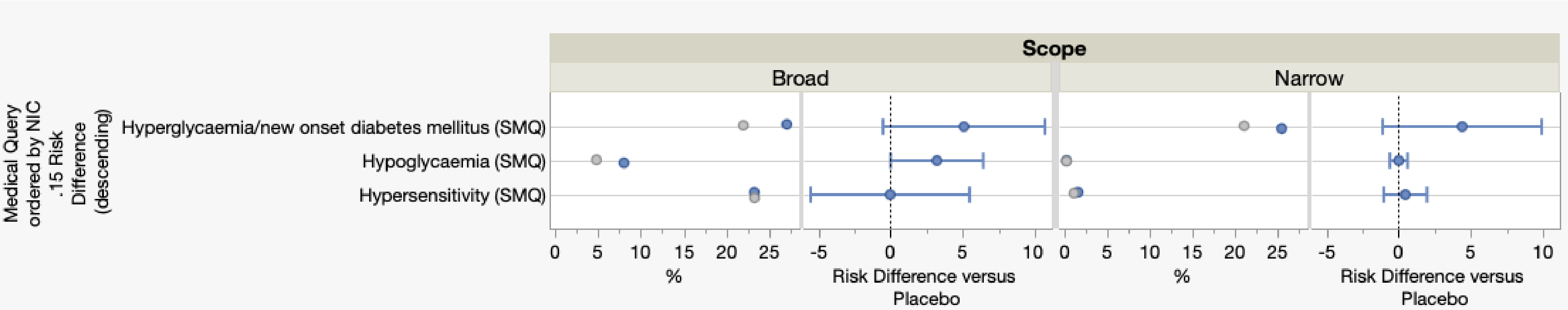
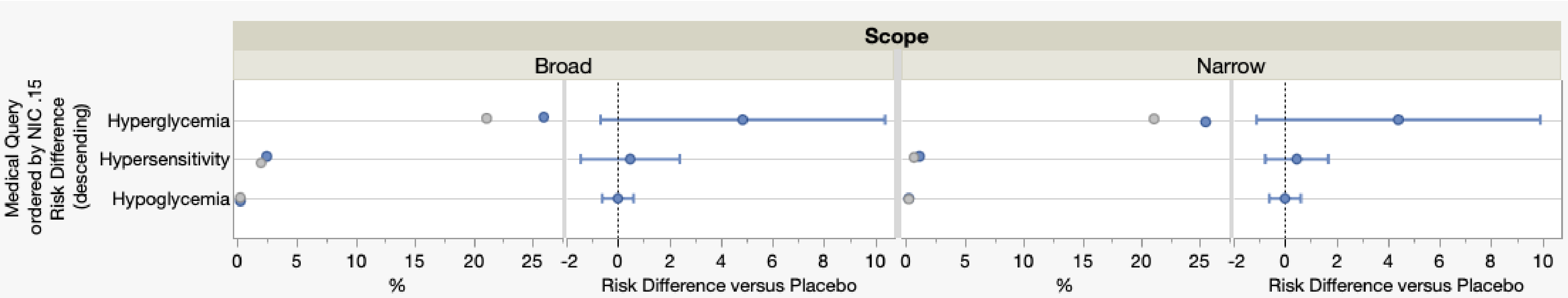
▼ Narrow Medical Queries and Terms			
Medical Query	NIC .15 (N = 447)	Placebo (N = 455)	Risk Difference for NIC .15 over Placebo
Acute Coronary Syndrome	4 (0.9)	4 (0.9)	0.0 (-1.2, 1.2)
Myocardial infarction	4 (0.9)	4 (0.9)	0.0 (-1.2, 1.2)
Abdominal Pain	1 (0.2)	1 (0.2)	0.0 (-0.6, 0.6)
Abdominal pain	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 Patterns

Adverse Events (AE)

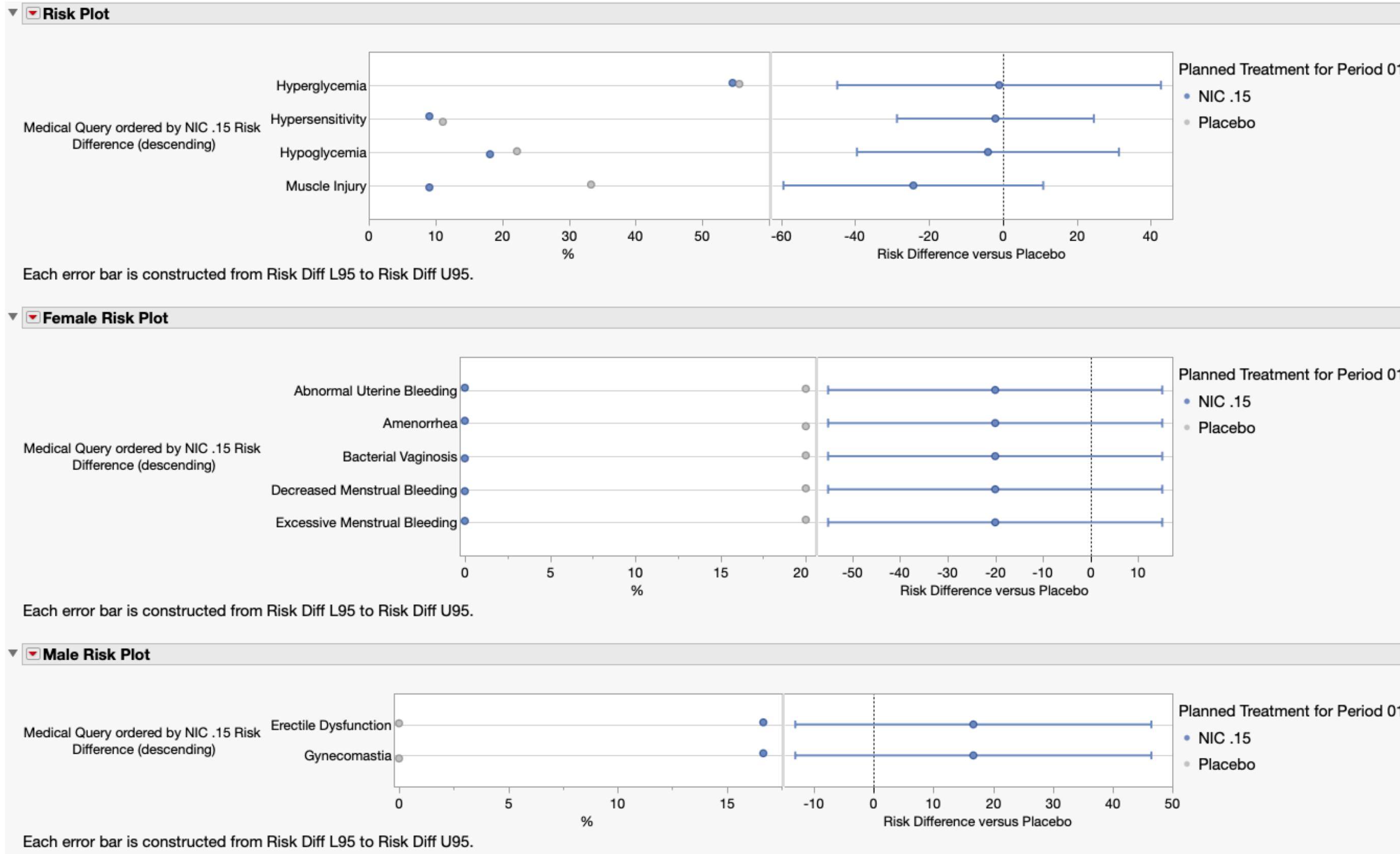
- Function input of a scope or term, some with a window and other AEs within the window
- Examples:
 - Hyperglycemia Criteria: Any PT from Hyperglycemia OCMQ Narrow
 - Hypoglycemia Criteria: Any Hypoglycemia OCMQ Narrow Term
 - Hypersensitivity Criteria: Category B adverse event and Category C adverse event within 7 days
 - Muscle Injury Criteria: [PT Myalgia + PT Muscular Weakness + (PT Myoglobin Urine Present OR PT Chromaturia)] with start date within 7 days

Algorithmic OCMQ Patterns

Laboratory Findings (LB)

- Function input of test name, comparator, result, units, post-baseline/change from baseline, fasting, occurrences
- Hyperglycemia Criteria Examples:
 - Fasting Plasma Glucose ≥ 126 mg/dL
 - ≥ 2 Plasma Glucoses > 180 mg/dL
 - Post Baseline HbA1c $\geq 6.5\%$
 - HbA1c Increase $\geq 0.3\%$ with Post Baseline HbA1c $\geq 5.7\%$
 - Change from Baseline Fasting Plasma Glucose ≥ 20 mg/dL with Post Baseline FPG > 100 mg/dL

Algorithmic OCMQ Plots



Algorithmic OCMQ Tables

Female Algorithmic Medical Queries			
Medical Query	Planned Treatment for Period 01		Risk Difference for NIC .15 over Placebo
	NIC .15 (N = 5)	Placebo (N = 5)	
Abnormal Uterine Bleeding	0 (0.0)	1 (20.0)	-20.0 (-55.1, 15.1)
Biological females only	0 (0.0)	1 (20.0)	-20.0 (-55.1, 15.1)
Amenorrhea	0 (0.0)	1 (20.0)	-20.0 (-55.1, 15.1)
Biological females only	0 (0.0)	1 (20.0)	-20.0 (-55.1, 15.1)
Bacterial Vaginosis	0 (0.0)	1 (20.0)	-20.0 (-55.1, 15.1)
Biological females only	0 (0.0)	1 (20.0)	-20.0 (-55.1, 15.1)
Decreased Menstrual Bleeding	0 (0.0)	1 (20.0)	-20.0 (-55.1, 15.1)
Biological females only	0 (0.0)	1 (20.0)	-20.0 (-55.1, 15.1)
Excessive Menstrual Bleeding	0 (0.0)	1 (20.0)	-20.0 (-55.1, 15.1)
Biological females only	0 (0.0)	1 (20.0)	-20.0 (-55.1, 15.1)

Male Algorithmic Medical Queries			
Medical Query	Planned Treatment for Period 01		Risk Difference for NIC .15 over Placebo
	NIC .15 (N = 6)	Placebo (N = 4)	
Erectile Dysfunction	1 (16.7)	0 (0.0)	16.7 (-13.2, 46.5)
Biological males only	1 (16.7)	0 (0.0)	16.7 (-13.2, 46.5)
Gynecomastia	1 (16.7)	0 (0.0)	16.7 (-13.2, 46.5)
Biological males only	1 (16.7)	0 (0.0)	16.7 (-13.2, 46.5)

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)
≥ 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 $> 5 \times$ 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)

Resources

- Office of New Drugs Custom Medical Queries
<https://www.fda.gov/drugs/development-resources/office-new-drugs-custom-medical-queries-ocmqs>
- Advanced Premarket Safety Analytics Workshop
<https://healthpolicy.duke.edu/sites/default/files/2022-09/Advancing%20Premarket%20Safety%20Analytics%20Final%20Slide%20Deck.pdf>
- FDA Standard Safety Tables and Figures
<https://www.fda.gov/drugs/development-resources/standard-safety-tables-and-figures-stfs>
- MedDRA Standardized Medical Queries
<https://www.meddra.org/how-to-use/tools/smq>

Resources

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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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Access

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