Table 14-5.01
Incidence of Treatment Emergent Adverse Events by Treatment Group

System Organ Class/ Preferred Term	Placebo (N=86) n(%)	[AEs]	Xanomeline Low Dose (N=84) n(%)	[AEs]	Xanomeline High Dose (N=84) n(%)	[AEs]	Fisher's Exact p-values: Placebo vs. Low Dose	Fisher's Exact p-values: Placebo vs. High Dose
ANY BODY SYSTEM	65 (75.6%)	[281]	77 (91.7%)	[412]	76 (90.5%)	[433]	0.007*	0.014*
CARDIAC DISORDERS	12 (14.0%)	[26]	13 (15.5%)	[30]	15 (17.9%)	[30]	0.831	0.534
SINUS BRADYCARDIA	2 (2.3%)	[2]	7 (8.3%)	[10]	8 (9.5%)	[12]	0.097*	0.056*
MYOCARDIAL INFARCTION	4 (4.7%)	[4]	2 (2.4%)	[4]	4 (4.8%)	[8]	0.682	>.99
ATRIAL FIBRILLATION	1 (1.2%)	[1]	1 (1.2%)	[1]	3 (3.6%)	[5]	>.99	0.365
ATRIAL FLUTTER	0		1 (1.2%)	[1]	1 (1.2%)	[2]	0.494	0.494
CARDIAC DISORDER	0		0		1 (1.2%)	[1]		0.494
SUPRAVENTRICULAR EXTRASYSTOLES	1 (1.2%)	[2]	1 (1.2%)	[2]	1 (1.2%)	[1]	>.99	>.99
VENTRICULAR EXTRASYSTOLES	0		2 (2.4%)	[4]	1 (1.2%)	[1]	0.243	0.494
ATRIAL HYPERTROPHY	1 (1.2%)	[2]	0		0		>.99	>.99
ATRIOVENTRICULAR BLOCK FIRST DEGREE	1 (1.2%)	[1]	1 (1.2%)	[1]	0		>.99	>.99
ATRIOVENTRICULAR BLOCK SECOND DEGREE	1 (1.2%)	[1]	0		0		>.99	>.99
BRADYCARDIA	1 (1.2%)	[4]	0		0		>.99	>.99
BUNDLE BRANCH BLOCK LEFT	1 (1.2%)	[1]	0		0		>.99	>.99
BUNDLE BRANCH BLOCK RIGHT	1 (1.2%)	[2]	1 (1.2%)	[1]	0		>.99	>.99

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Note: Percentages are based on the number of subjects in the safety population within each treatment group.
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CARDIAC FAILURE CONGESTIVE	1 (1.2%) [1]	0	0	>.99	>.99
PALPITATIONS	0	2 (2.4%) [2]	0	0.243	
SINUS ARRHYTHMIA	1 (1.2%) [2]	0	0	>.99	>.99
SUPRAVENTRICULAR TACHYCARDIA	0	1 (1.2%) [2]	0	0.494	
TACHYCARDIA	1 (1.2%) [2]	0	0	>.99	>.99
VENTRICULAR HYPERTROPHY	1 (1.2%) [1]	0	0	>.99	>.99
WOLFF-PARKINSON-WHITE SYNDROME	0	1 (1.2%) [2]	0	0.494	
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0	1 (1.2%) [1]	2 (2.4%) [2]	0.494	0.243
VENTRICULAR SEPTAL DEFECT	0	1 (1.2%) [1]	2 (2.4%) [2]	0.494	0.243
EAR AND LABYRINTH DISORDERS	1 (1.2%) [2]	2 (2.4%) [2]	1 (1.2%) [1]	0.618	>.99
VERTIGO	0	1 (1.2%) [1]	1 (1.2%) [1]	0.494	0.494
CERUMEN IMPACTION	0	1 (1.2%) [1]	0	0.494	
EAR PAIN	1 (1.2%) [2]	0	0	>.99	>.99
EYE DISORDERS	2 (2.3%) [5]	2 (2.4%) [2]	1 (1.2%) [2]	>.99	>.99

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System Organ Class/ Preferred Term	Placebo (N=86) n(%) [AEs]	Xanomeline Low Dose (N=84) n(%) [AEs]	Xanomeline High Dose (N=84) n(%) [AEs]	Fisher's Exact p-values Placebo vs. Low Dose	Fisher's Exact p-values Placebo vs. High Dose
VISION BLURRED	0	1 (1.2%) [1]	1 (1.2%) [2]	0.494	0.494
CONJUNCTIVAL HAEMORRHAGE	0	1 (1.2%) [1]	0	0.494	
CONJUNCTIVITIS	1 (1.2%) [2]	0	0	>.99	>.99
EYE ALLERGY	1 (1.2%) [1]	0	0	>.99	>.99
EYE PRURITUS	1 (1.2%) [1]	0	0	>.99	>.99
EYE SWELLING	1 (1.2%) [1]	0	0	>.99	>.99
GASTROINTESTINAL DISORDERS	17 (19.8%) [26]	14 (16.7%) [22]	20 (23.8%) [36]	0.692	0.580
VOMITING	3 (3.5%) [3]	3 (3.6%) [4]	7 (8.3%) [9]	>.99	0.208
NAUSEA	3 (3.5%) [3]	3 (3.6%) [5]	6 (7.1%) [13]	>.99	0.326
DIARRHOEA	9 (10.5%) [10]	4 (4.8%) [5]	4 (4.8%) [4]	0.248	0.248
SALIVARY HYPERSECRETION	0	0	4 (4.8%) [5]		0.057*
ABDOMINAL DISCOMFORT	0	0	1 (1.2%) [1]		0.494
ABDOMINAL PAIN	1 (1.2%) [1]	3 (3.6%) [3]	1 (1.2%) [2]	0.365	>.99
GASTROINTESTINAL HAEMORRHAGE	0	0	1 (1.2%) [1]		0.494
STOMACH DISCOMFORT	0	0	1 (1.2%) [1]		0.494
CONSTIPATION	1 (1.2%) [1]	0	0	>.99	>.99
DYSPEPSIA	1 (1.2%) [2]	1 (1.2%) [2]	0	>.99	>.99
DYSPHAGIA	0	1 (1.2%) [1]	0	0.494	

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Note: Percentages are based on the number of subjects in the safety population within each treatment group.
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Source: programs/t-14-5-01.R *19:29 Tuesday, June 16, 2020*

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Incidence of Treatment Emergent Adverse Events by Treatment Group

System Organ Class/ Preferred Term	Placebo (N=86) n(%) [AEs]	Xanomeline Low Dose (N=84) n(%) [AEs]	Xanomeline High Dose (N=84) n(%) [AEs]	Fisher's Exact p-values Placebo vs. Low Dose	Fisher's Exact p-values Placebo vs. High Dose
FLATULENCE	1 (1.2%) [2]	0	0	>.99	>.99
GASTROOESOPHAGEAL REFLUX DISEASE	1 (1.2%) [1]	0	0	>.99	>.99
GLOSSITIS	1 (1.2%) [1]	0	0	>.99	>.99
HIATUS HERNIA	1 (1.2%) [2]	0	0	>.99	>.99
RECTAL HAEMORRHAGE	0	1 (1.2%) [2]	0	0.494	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	21 (24.4%) [46]	47 (56.0%) [118]	40 (47.6%) [124]	0.000*	0.002*
APPLICATION SITE PRURITUS	6 (7.0%) [10]	22 (26.2%) [32]	22 (26.2%) [35]	0.001*	0.001*
APPLICATION SITE ERYTHEMA	3 (3.5%) [3]	12 (14.3%) [20]	15 (17.9%) [23]	0.015*	0.002*
APPLICATION SITE IRRITATION	3 (3.5%) [7]	9 (10.7%) [18]	9 (10.7%) [16]	0.078*	0.078*
APPLICATION SITE DERMATITIS	5 (5.8%) [9]	9 (10.7%) [15]	7 (8.3%) [12]	0.277	0.563
APPLICATION SITE VESICLES	1 (1.2%) [2]	4 (4.8%) [5]	6 (7.1%) [6]	0.208	0.062*
FATIGUE	1 (1.2%) [2]	5 (6.0%) [5]	5 (6.0%) [5]	0.115*	0.115*
APPLICATION SITE PAIN	0	0	2 (2.4%) [2]		0.243
APPLICATION SITE PERSPIRATION	0	0	2 (2.4%) [3]		0.243
APPLICATION SITE SWELLING	0	1 (1.2%) [1]	2 (2.4%) [3]	0.494	0.243
CHEST DISCOMFORT	0	0	2 (2.4%) [2]		0.243

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CHEST PAIN	0	0	2 (2.4%) [2]		0.243
MALAISE	0	1 (1.2%) [2]	2 (2.4%) [3]	0.494	0.243
OEDEMA PERIPHERAL	2 (2.3%) [3]	1 (1.2%) [1]	2 (2.4%) [3]	>.99	>.99
APPLICATION SITE DISCHARGE	0	0	1 (1.2%) [1]		0.494
APPLICATION SITE REACTION	1 (1.2%) [2]	0	1 (1.2%) [1]	>.99	>.99
APPLICATION SITE URTICARIA	0	2 (2.4%) [2]	1 (1.2%) [1]	0.243	0.494
ASTHENIA	1 (1.2%) [2]	0	1 (1.2%) [1]	>.99	>.99
CHILLS	1 (1.2%) [3]	1 (1.2%) [2]	1 (1.2%) [1]	>.99	>.99
FEELING ABNORMAL	0	0	1 (1.2%) [1]		0.494
FEELING COLD	0	0	1 (1.2%) [1]		0.494
PAIN	0	1 (1.2%) [2]	1 (1.2%) [1]	0.494	0.494
PYREXIA	2 (2.3%) [2]	0	1 (1.2%) [1]	0.497	>.99
APPLICATION SITE BLEEDING	0	1 (1.2%) [1]	0	0.494	
APPLICATION SITE DESQUAMATION	0	1 (1.2%) [1]	0	0.494	
APPLICATION SITE DISCOLOURATION	0	1 (1.2%) [1]	0	0.494	
APPLICATION SITE INDURATION	1 (1.2%) [1]	0	0	>.99	>.99
APPLICATION SITE WARMTH	0	1 (1.2%) [2]	0	0.494	
INFLAMMATION	0	1 (1.2%) [1]	0	0.494	

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OEDEMA	0	2 (2.4%) [2]	0	0.243	
SECRETION DISCHARGE	0	1 (1.2%) [2]	0	0.494	
SUDDEN DEATH	0	1 (1.2%) [1]	0	0.494	
SWELLING	0	1 (1.2%) [1]	0	0.494	
ULCER	0	1 (1.2%) [1]	0	0.494	
HEPATOBILIARY DISORDERS	1 (1.2%) [1]	0	0	>.99	>.99
HYPERBILIRUBINAEMIA	1 (1.2%) [1]	0	0	>.99	>.99
IMMUNE SYSTEM DISORDERS	0	1 (1.2%) [2]	0	0.494	
HYPERSENSITIVITY	0	1 (1.2%) [2]	0	0.494	
INFECTIONS AND INFESTATIONS	16 (18.6%) [35]	9 (10.7%) [16]	13 (15.5%) [20]	0.194	0.685
NASOPHARYNGITIS	2 (2.3%) [4]	4 (4.8%) [9]	6 (7.1%) [8]	0.441	0.166
UPPER RESPIRATORY TRACT INFECTION	6 (7.0%) [12]	1 (1.2%) [2]	3 (3.6%) [5]	0.117*	0.496
CYSTITIS	1 (1.2%) [1]	0	1 (1.2%) [1]	>.99	>.99
HORDEOLUM	0	0	1 (1.2%) [1]		0.494
INFLUENZA	1 (1.2%) [2]	1 (1.2%) [1]	1 (1.2%) [1]	>.99	>.99

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LOWER RESPIRATORY TRACT INFECTION	0	0	1 (1.2%) [2]		0.494
RHINITIS	0	0	1 (1.2%) [1]		0.494
URINARY TRACT INFECTION	2 (2.3%) [4]	0	1 (1.2%) [1]	0.497	>.99
BRONCHITIS	1 (1.2%) [1]	0	0	>.99	>.99
CELLULITIS	0	1 (1.2%) [1]	0	0.494	
CERVICITIS	1 (1.2%) [2]	0	0	>.99	>.99
EAR INFECTION	2 (2.3%) [4]	0	0	0.497	0.497
GASTROENTERITIS VIRAL	1 (1.2%) [1]	0	0	>.99	>.99
LOCALISED INFECTION	1 (1.2%) [2]	0	0	>.99	>.99
PNEUMONIA	0	1 (1.2%) [2]	0	0.494	
VAGINAL MYCOSIS	1 (1.2%) [2]	0	0	>.99	>.99
VIRAL INFECTION	0	1 (1.2%) [1]	0	0.494	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	4 (4.7%) [9]	5 (6.0%) [12]	5 (6.0%) [8]	0.745	0.745
CONTUSION	1 (1.2%) [1]	1 (1.2%) [3]	2 (2.4%) [3]	>.99	0.618
HIP FRACTURE	1 (1.2%) [2]	0	2 (2.4%) [2]	>.99	0.618
EXCORIATION	2 (2.3%) [3]	1 (1.2%) [2]	1 (1.2%) [1]	>.99	>.99

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FACIAL BONES FRACTURE	0	0	1 (1.2%) [1]		0.494
FALL	1 (1.2%) [2]	2 (2.4%) [2]	1 (1.2%) [1]	0.618	>.99
JOINT DISLOCATION	0	1 (1.2%) [1]	0	0.494	
SKIN LACERATION	1 (1.2%) [1]	2 (2.4%) [2]	0	0.618	>.99
WOUND	0	1 (1.2%) [2]	0	0.494	
INVESTIGATIONS	10 (11.6%) [19]	6 (7.1%) [7]	6 (7.1%) [8]	0.432	0.432
BIOPSY	0	0	1 (1.2%) [1]		0.494
BIOPSY PROSTATE	0	0	1 (1.2%) [1]		0.494
BLOOD CHOLESTEROL INCREASED	0	0	1 (1.2%) [1]		0.494
BLOOD GLUCOSE INCREASED	0	1 (1.2%) [1]	1 (1.2%) [2]	0.494	0.494
ELECTROCARDIOGRAM T WAVE INVERSION	2 (2.3%) [3]	1 (1.2%) [1]	1 (1.2%) [1]	>.99	>.99
WEIGHT DECREASED	0	0	1 (1.2%) [2]		0.494
BLOOD ALKALINE PHOSPHATASE INCREASED	1 (1.2%) [1]	0	0	>.99	>.99
BLOOD CREATINE PHOSPHOKINASE INCREASED	1 (1.2%) [2]	0	0	>.99	>.99
BLOOD URINE PRESENT	1 (1.2%) [1]	0	0	>.99	>.99
BODY TEMPERATURE INCREASED	0	1 (1.2%) [1]	0	0.494	

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CYSTOSCOPY	1 (1.2%) [1]	0	0	>.99	>.99
ELECTROCARDIOGRAM ST SEGMENT DEPRESSION	4 (4.7%) [4]	1 (1.2%) [2]	0	0.368	0.121*
ELECTROCARDIOGRAM T WAVE AMPLITUDE DECREASED	1 (1.2%) [1]	1 (1.2%) [1]	0	>.99	>.99
HEART RATE INCREASED	1 (1.2%) [2]	0	0	>.99	>.99
HEART RATE IRREGULAR	1 (1.2%) [4]	0	0	>.99	>.99
NASAL MUCOSA BIOPSY	0	1 (1.2%) [1]	0	0.494	
METABOLISM AND NUTRITION DISORDERS	6 (7.0%) [8]	1 (1.2%) [1]	2 (2.4%) [4]	0.117*	0.278
DECREASED APPETITE	1 (1.2%) [2]	0	1 (1.2%) [2]	>.99	>.99
INCREASED APPETITE	1 (1.2%) [2]	0	1 (1.2%) [2]	>.99	>.99
DEHYDRATION	1 (1.2%) [1]	0	0	>.99	>.99
DIABETES MELLITUS	1 (1.2%) [1]	0	0	>.99	>.99
FOOD CRAVING	1 (1.2%) [1]	1 (1.2%) [1]	0	>.99	>.99
HYPONATRAEMIA	1 (1.2%) [1]	0	0	>.99	>.99
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	4 (4.7%) [6]	7 (8.3%) [10]	7 (8.3%) [10]	0.367	0.367

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BACK PAIN	1 (1.2%) [2]	1 (1.2%) [1]	3 (3.6%) [4]	>.99	0.365
ARTHRALGIA	1 (1.2%) [1]	2 (2.4%) [4]	1 (1.2%) [1]	0.618	>.99
ARTHRITIS	0	0	1 (1.2%) [1]		0.494
FLANK PAIN	0	0	1 (1.2%) [1]		0.494
MUSCLE SPASMS	0	1 (1.2%) [1]	1 (1.2%) [2]	0.494	0.494
MYALGIA	0	0	1 (1.2%) [1]		0.494
MUSCULAR WEAKNESS	0	1 (1.2%) [2]	0	0.494	
PAIN IN EXTREMITY	1 (1.2%) [1]	0	0	>.99	>.99
SHOULDER PAIN	1 (1.2%) [2]	2 (2.4%) [2]	0	0.618	>.99
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	2 (2.4%) [3]	1 (1.2%) [1]	0.243	0.494
PROSTATE CANCER	0	0	1 (1.2%) [1]		0.494
COLON CANCER	0	1 (1.2%) [1]	0	0.494	
MALIGNANT FIBROUS HISTIOCYTOMA	0	1 (1.2%) [2]	0	0.494	
NERVOUS SYSTEM DISORDERS	8 (9.3%) [11]	20 (23.8%) [40]	25 (29.8%) [41]	0.013*	0.001*
DIZZINESS	2 (2.3%) [3]	8 (9.5%) [13]	11 (13.1%) [15]	0.056*	0.009*

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HEADACHE	3 (3.5%) [3]	3 (3.6%) [4]	5 (6.0%) [8]	>.99	0.493
SYNCOPE	0	4 (4.8%) [6]	3 (3.6%) [4]	0.057*	0.118*
BURNING SENSATION	0	0	2 (2.4%) [2]		0.243
AMNESIA	0	0	1 (1.2%) [2]		0.494
COGNITIVE DISORDER	0	0	1 (1.2%) [1]		0.494
HYPERSOMNIA	0	0	1 (1.2%) [1]		0.494
LETHARGY	0	1 (1.2%) [1]	1 (1.2%) [1]	0.494	0.494
PARAESTHESIA	0	0	1 (1.2%) [1]		0.494
PAROSMIA	0	0	1 (1.2%) [2]		0.494
PARTIAL SEIZURES WITH SECONDARY GENERALISATION	0	0	1 (1.2%) [1]		0.494
SOMNOLENCE	2 (2.3%) [3]	3 (3.6%) [5]	1 (1.2%) [1]	0.680	>.99
SYNCOPE VASOVAGAL	0	0	1 (1.2%) [1]		0.494
TRANSIENT ISCHAEMIC ATTACK	0	2 (2.4%) [3]	1 (1.2%) [1]	0.243	0.494
BALANCE DISORDER	0	1 (1.2%) [3]	0	0.494	
COMPLEX PARTIAL SEIZURES	0	1 (1.2%) [1]	0	0.494	
COORDINATION ABNORMAL	0	1 (1.2%) [1]	0	0.494	
HEMIANOPIA HOMONYMOUS	0	1 (1.2%) [1]	0	0.494	
PARAESTHESIA ORAL	0	1 (1.2%) [1]	0	0.494	

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Note: P-values are based on Fisher's Exact test for the comparison of placebo versus each active treatment group. An asterisk is appended to p-values that are less than 0.15.
Note: The column [AE] represents the total number of times an event was recorded.

Table 14-5.01
Incidence of Treatment Emergent Adverse Events by Treatment Group

System Organ Class/ Preferred Term	Placebo (N=86) n(%) [AEs]	Xanomeline Low Dose (N=84) n(%) [AEs]	Xanomeline High Dose (N=84) n(%) [AEs]	Fisher's Exact p-values Placebo vs. Low Dose	Fisher's Exact p-values Placebo vs. High Dose
PARKINSON'S DISEASE	1 (1.2%) [1]	0	0	>.99	>.99
PSYCHOMOTOR HYPERACTIVITY	1 (1.2%) [1]	0	0	>.99	>.99
STUPOR	0	1 (1.2%) [1]	0	0.494	
PSYCHIATRIC DISORDERS	10 (11.6%) [12]	10 (11.9%) [14]	8 (9.5%) [11]	>.99	0.804
INSOMNIA	2 (2.3%) [3]	0	2 (2.4%) [2]	0.497	>.99
AGITATION	2 (2.3%) [2]	2 (2.4%) [2]	1 (1.2%) [1]	>.99	>.99
CONFUSIONAL STATE	2 (2.3%) [2]	3 (3.6%) [3]	1 (1.2%) [1]	0.680	>.99
DELIRIUM	0	0	1 (1.2%) [1]		0.494
DELUSION	1 (1.2%) [1]	0	1 (1.2%) [1]	>.99	>.99
HALLUCINATION	0	0	1 (1.2%) [1]		0.494
HALLUCINATION, VISUAL	0	0	1 (1.2%) [1]		0.494
LIBIDO DECREASED	0	0	1 (1.2%) [1]		0.494
LISTLESS	0	0	1 (1.2%) [1]		0.494
NIGHTMARE	0	0	1 (1.2%) [1]		0.494
ANXIETY	0	3 (3.6%) [4]	0	0.118*	
COMPLETED SUICIDE	1 (1.2%) [1]	0	0	>.99	>.99
DEPRESSED MOOD	0	1 (1.2%) [2]	0	0.494	
DISORIENTATION	1 (1.2%) [1]	0	0	>.99	>.99

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IRRITABILITY	1 (1.2%) [2]	1 (1.2%) [1]	0	>.99	>.99
RESTLESSNESS	0	1 (1.2%) [2]	0	0.494	
RENAL AND URINARY DISORDERS	4 (4.7%) [5]	3 (3.6%) [3]	3 (3.6%) [4]	>.99	>.99
CALCULUS URETHRAL	0	0	1 (1.2%) [1]		0.494
MICTURITION URGENCY	1 (1.2%) [1]	1 (1.2%) [1]	1 (1.2%) [2]	>.99	>.99
NEPHROLITHIASIS	1 (1.2%) [1]	0	1 (1.2%) [1]	>.99	>.99
DYSURIA	1 (1.2%) [1]	1 (1.2%) [1]	0	>.99	>.99
INCONTINENCE	0	1 (1.2%) [1]	0	0.494	
POLLAKIURIA	1 (1.2%) [2]	0	0	>.99	>.99
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2 (2.3%) [4]	0	1 (1.2%) [1]	0.497	>.99
BENIGN PROSTATIC HYPERPLASIA	1 (1.2%) [2]	0	1 (1.2%) [1]	>.99	>.99
PELVIC PAIN	1 (1.2%) [2]	0	0	>.99	>.99
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	8 (9.3%) [12]	9 (10.7%) [14]	10 (11.9%) [22]	0.803	0.626
COUGH	1 (1.2%) [1]	5 (6.0%) [7]	5 (6.0%) [7]	0.115*	0.115*

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Note: P-values are based on Fisher's Exact test for the comparison of placebo versus each active treatment group. An asterisk is appended to p-values that are less than 0.15.
Note: The column [AE] represents the total number of times an event was recorded.

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Incidence of Treatment Emergent Adverse Events by Treatment Group

System Organ Class/ Preferred Term	Placebo (N=86) n(%) [AEs]	Xanomeline Low Dose (N=84) n(%) [AEs]	Xanomeline High Dose (N=84) n(%) [AEs]	Fisher's Exact p-values Placebo vs. Low Dose	Fisher's Exact p-values Placebo vs. High Dose
NASAL CONGESTION	3 (3.5%) [3]	1 (1.2%) [1]	3 (3.6%) [4]	0.621	>.99
EPISTAXIS	0	1 (1.2%) [1]	2 (2.4%) [2]	0.494	0.243
ALLERGIC GRANULOMATOUS ANGIITIS	0	0	1 (1.2%) [1]		0.494
DYSPNOEA	1 (1.2%) [1]	1 (1.2%) [1]	1 (1.2%) [1]	>.99	>.99
PHARYNGEAL ERYTHEMA	0	0	1 (1.2%) [2]		0.494
PHARYNGOLARYNGEAL PAIN	0	1 (1.2%) [1]	1 (1.2%) [1]	0.494	0.494
PRODUCTIVE COUGH	0	0	1 (1.2%) [1]		0.494
RESPIRATORY TRACT CONGESTION	0	0	1 (1.2%) [1]		0.494
RHINORRHOEA	0	1 (1.2%) [2]	1 (1.2%) [2]	0.494	0.494
DYSPHONIA	0	1 (1.2%) [1]	0	0.494	
EMPHYSEMA	1 (1.2%) [1]	0	0	>.99	>.99
HAEMOPTYSIS	1 (1.2%) [2]	0	0	>.99	>.99
POSTNASAL DRIP	1 (1.2%) [2]	0	0	>.99	>.99
RALES	1 (1.2%) [2]	0	0	>.99	>.99
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	20 (23.3%) [45]	39 (46.4%) [111]	40 (47.6%) [104]	0.002*	0.001*
PRURITUS	8 (9.3%) [11]	21 (25.0%) [31]	26 (31.0%) [38]	0.008*	0.000*

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Table 14-5.01
Incidence of Treatment Emergent Adverse Events by Treatment Group

	Placebo (N=86)		Xanomeline Low Dose (N=84)		Xanomeline High Dose (N=84)		Fisher's Exact p-values	
System Organ Class/ Preferred Term	n(%)	[AEs]	n(%)	[AEs]	n(%)	[AEs]	Placebo vs. Low Dose	Placebo vs. High Dose
ERYTHEMA	8 (9.3%)	[12]	14 (16.7%)	[22]	14 (16.7%)	[22]	0.175	0.175
RASH	5 (5.8%)	[9]	13 (15.5%)	[18]	9 (10.7%)	[15]	0.048*	0.277
HYPERHIDROSIS	2 (2.3%)	[2]	4 (4.8%)	[5]	8 (9.5%)	[10]	0.441	0.056*
SKIN IRRITATION	3 (3.5%)	[4]	6 (7.1%)	[13]	5 (6.0%)	[8]	0.326	0.493
RASH PRURITIC	0		1 (1.2%)	[2]	2 (2.4%)	[3]	0.494	0.243
ACTINIC KERATOSIS	0		0		1 (1.2%)	[1]		0.494
BLISTER	0		5 (6.0%)	[8]	1 (1.2%)	[2]	0.028*	0.494
PRURITUS GENERALISED	0		1 (1.2%)	[4]	1 (1.2%)	[1]	0.494	0.494
RASH MACULO-PAPULAR	0		0		1 (1.2%)	[1]		0.494
SKIN ODOUR ABNORMAL	0		0		1 (1.2%)	[1]		0.494
URTICARIA	0		1 (1.2%)	[3]	1 (1.2%)	[2]	0.494	0.494
ALOPECIA	1 (1.2%)	[1]	0		0		>.99	>.99
COLD SWEAT	1 (1.2%)	[3]	0		0		>.99	>.99
DERMATITIS CONTACT	0		1 (1.2%)	[2]	0		0.494	
DRUG ERUPTION	1 (1.2%)	[1]	0		0		>.99	>.99
RASH ERYTHEMATOUS	0		1 (1.2%)	[1]	0		0.494	
SKIN EXFOLIATION	0		1 (1.2%)	[2]	0		0.494	
SKIN ULCER	1 (1.2%)	[2]	0		0		>.99	>.99

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Note: Adverse events are coded using MedDRA.
Note: Percentages are based on the number of subjects in the safety population within each treatment group.
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SOCIAL CIRCUMSTANCES	0	0	1 (1.2%) [1]		0.494
ALCOHOL USE	0	0	1 (1.2%) [1]		0.494
SURGICAL AND MEDICAL PROCEDURES	2 (2.3%) [2]	1 (1.2%) [1]	2 (2.4%) [2]	>.99	>.99
ACROCHORDON EXCISION	0	0	1 (1.2%) [1]		0.494
SKIN LESION EXCISION	0	0	1 (1.2%) [1]		0.494
CATARACT OPERATION	1 (1.2%) [1]	1 (1.2%) [1]	0	>.99	>.99
EYE LASER SURGERY	1 (1.2%) [1]	0	0	>.99	>.99
VASCULAR DISORDERS	3 (3.5%) [7]	3 (3.6%) [3]	1 (1.2%) [1]	>.99	0.621
WOUND HAEMORRHAGE	0	0	1 (1.2%) [1]		0.494
HOT FLUSH	0	1 (1.2%) [1]	0	0.494	
HYPERTENSION	1 (1.2%) [2]	1 (1.2%) [1]	0	>.99	>.99
HYPOTENSION	2 (2.3%) [3]	1 (1.2%) [1]	0	>.99	0.497
ORTHOSTATIC HYPOTENSION	1 (1.2%) [2]	0	0	>.99	>.99

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