Adverse Events

Jagadish

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Step 1: Get the ADSL and ADAE and merge them on population

```
adsl <- adsl %>% filter(SAFFL=='Y') %>% select(USUBJID, TRTA=TRT01A, TRTAN=TRT01AN)
cnt <- adsl %>% group_by(TRTAN,TRTA) %>% count()
trt <- adsl %>% distinct(TRTAN) %>% pull(TRTAN)

txt2 <- map2(trt,1:3, \(x,y) {
     val <- cnt %>% filter(TRTAN==x) %>% pull(n)
     txt <- paste0('t',y)
     assign(txt,val, envir = globalenv())
}
    )

adae <- adae %>% select(-c(TRTA, TRTAN)) %>% inner_join(adsl, by='USUBJID')

adae <- adae %>% select(USUBJID, TRTA, TRTAN, AEBODSYS, AEDECOD) %>% distinct() %>%
  mutate(all='Subjects with any Adverse Events',
         across(c(AEBODSYS, AEDECOD), ~ str_to_title(.)))
```

Step 2: Use the Tplyr package to generate the summary table of Adverse Events

```
dt <- Tplyr::tplyr_table(adae, TRTA) %>%
  set_pop_data(adsl) %>%
  set_pop_treat_var(TRTA) %>%
  set_pop_where(TRUE) %>%
  Tplyr::add_layer(group_count(all, by='Subjects with any Adverse Events') %>%
                     set_format_strings(f_str("xxx (xx.x%)", distinct_n, distinct_pct))) %>%
  set_distinct_by(USUBJID) %>%
  Tplyr::add_layer(group_count(vars(AEBODSYS,AEDECOD)) %>%
                     set_format_strings(f_str("xxx (xx.x%)", distinct_n, distinct_pct))) %>%
  set_distinct_by(USUBJID) %>%
  Tplyr::build()

dt <- dt %>% mutate(ord_layer_1=ifelse(row_number()!=1,ord_layer_1+1,ord_layer_1))

names(dt) <- str_replace_all(names(dt),'\\s','_')
```

Step 3: Use the reporter package to generate the report from the dataframe

```
tbl <- create_table(dt) %>%
  define(row_label1,  visible = FALSE) %>%
  define(row_label2, label = "", indent = .25) %>%
  define(var1_Placebo, label = "Placebo", align = "left", n = txt2$t1) %>%
  define(var1_Xanomeline_High_Dose, label = "Xanomeline High Dose", align = "left", n = txt2$t3) %>%
  define(var1_Xanomeline_Low_Dose, label = "Xanomeline Low Dose", align = "left", n = txt2$t2) %>%
  define(ord_layer_index, visible = FALSE) %>%
  define(ord_layer_1, visible = FALSE, blank_after = TRUE) %>%
  define(ord_layer_2, visible = FALSE)

pth <- file.path(                                    , "test1.rtf")


rpt <- create_report(pth,
                     output_type = "RTF",
                     orientation = "landscape") %>%
  titles("Table 1.0",
         "Summary of Adverse Events",
         "Population: Safety") %>%
  set_margins(top = 1, bottom = 1) %>%
  add_content(tbl)

write_report(rpt)
```

```
## # A report specification: 9 pages
## - file_path: '
## - output_type: RTF
## - units: inches
## - orientation: landscape
## - margins: top 1 bottom 1 left 1 right 1
## - line size/count: 107/41
## - title 1: 'Table 1.0'
## - title 2: 'Summary of Adverse Events'
## - title 3: 'Population: Safety'
## - content:
## # A table specification:
## - data: tibble 'dt' 266 rows 8 cols
## - show_cols: all
## - use_attributes: all
## - define: row_label1 visible='FALSE'
## - define: row_label2 ''
## - define: var1_Placebo 'Placebo' align='left'
## - define: var1_Xanomeline_High_Dose 'Xanomeline High Dose' align='left'
## - define: var1_Xanomeline_Low_Dose 'Xanomeline Low Dose' align='left'
## - define: ord_layer_index visible='FALSE'
## - define: ord_layer_1 visible='FALSE'
## - define: ord_layer_2 visible='FALSE'
```

Table 1.0
Summary of Adverse Events
Population: Safety

	Placebo (N=86)	Xanomeline High Dose (N=84)	Xanomeline Low Dose (N=84)
Subjects with any Adverse Events	69 (80.2%)	79 (94.0%)	77 (91.7%)
Cardiac Disorders	13 (15.1%)	18 (21.4%)	13 (15.5%)
Atrial Fibrillation	1 (1.2%)	3 (3.6%)	1 (1.2%)
Atrial Flutter	0 (0.0%)	1 (1.2%)	1 (1.2%)
Atrial Hypertrophy	1 (1.2%)	0 (0.0%)	0 (0.0%)
Atrioventricular Block First Degree	1 (1.2%)	0 (0.0%)	1 (1.2%)
Atrioventricular Block Second Degree	2 (2.3%)	3 (3.6%)	0 (0.0%)
Bradycardia	1 (1.2%)	0 (0.0%)	0 (0.0%)
Bundle Branch Block Left	1 (1.2%)	0 (0.0%)	0 (0.0%)
Bundle Branch Block Right	1 (1.2%)	0 (0.0%)	1 (1.2%)
Cardiac Disorder	0 (0.0%)	1 (1.2%)	0 (0.0%)
Cardiac Failure Congestive	1 (1.2%)	0 (0.0%)	0 (0.0%)
Myocardial Infarction	4 (4.7%)	4 (4.8%)	2 (2.4%)
Palpitations	0 (0.0%)	0 (0.0%)	2 (2.4%)
Sinus Arrhythmia	1 (1.2%)	0 (0.0%)	0 (0.0%)
Sinus Bradycardia	2 (2.3%)	8 (9.5%)	7 (8.3%)
Supraventricular Extrasystoles	1 (1.2%)	1 (1.2%)	1 (1.2%)
Supraventricular Tachycardia	0 (0.0%)	0 (0.0%)	1 (1.2%)
Tachycardia	1 (1.2%)	0 (0.0%)	0 (0.0%)
Ventricular Extrasystoles	0 (0.0%)	1 (1.2%)	2 (2.4%)
Ventricular Hypertrophy	1 (1.2%)	0 (0.0%)	0 (0.0%)
Wolff-Parkinson-White Syndrome	0 (0.0%)	0 (0.0%)	1 (1.2%)
Congenital, Familial And Genetic Disorders	0 (0.0%)	2 (2.4%)	1 (1.2%)
Ventricular Septal Defect	0 (0.0%)	2 (2.4%)	1 (1.2%)
Ear And Labyrinth Disorders	1 (1.2%)	1 (1.2%)	2 (2.4%)
Cerumen Impaction	0 (0.0%)	0 (0.0%)	1 (1.2%)
Ear Pain	1 (1.2%)	0 (0.0%)	0 (0.0%)
Tinnitus	0 (0.0%)	0 (0.0%)	1 (1.2%)
Vertigo	0 (0.0%)	1 (1.2%)	1 (1.2%)

Table 1.0
Summary of Adverse Events
Population: Safety

	Placebo (N=86)	Xanomeline High Dose (N=84)	Xanomeline Low Dose (N=84)
Eye Disorders	4 (4.7%)	1 (1.2%)	2 (2.4%)
Conjunctival Haemorrhage	0 (0.0%)	0 (0.0%)	1 (1.2%)
Conjunctivitis	2 (2.3%)	0 (0.0%)	0 (0.0%)
Eye Allergy	1 (1.2%)	0 (0.0%)	0 (0.0%)
Eye Pruritus	1 (1.2%)	0 (0.0%)	0 (0.0%)
Eye Swelling	1 (1.2%)	0 (0.0%)	0 (0.0%)
Glaucoma	1 (1.2%)	0 (0.0%)	0 (0.0%)
Vision Blurred	0 (0.0%)	1 (1.2%)	1 (1.2%)
Gastrointestinal Disorders	17 (19.8%)	21 (25.0%)	15 (17.9%)
Abdominal Discomfort	0 (0.0%)	1 (1.2%)	0 (0.0%)
Abdominal Pain	1 (1.2%)	1 (1.2%)	3 (3.6%)
Constipation	1 (1.2%)	0 (0.0%)	0 (0.0%)
Diarrhoea	9 (10.5%)	4 (4.8%)	5 (6.0%)
Dyspepsia	1 (1.2%)	1 (1.2%)	1 (1.2%)
Dysphagia	0 (0.0%)	0 (0.0%)	1 (1.2%)
Flatulence	1 (1.2%)	0 (0.0%)	0 (0.0%)
Gastrointestinal Haemorrhage	0 (0.0%)	1 (1.2%)	0 (0.0%)
Gastrooesophageal Reflux Disease	1 (1.2%)	0 (0.0%)	0 (0.0%)
Glossitis	1 (1.2%)	0 (0.0%)	0 (0.0%)
Hiatus Hernia	1 (1.2%)	0 (0.0%)	0 (0.0%)
Nausea	3 (3.5%)	6 (7.1%)	3 (3.6%)
Rectal Haemorrhage	0 (0.0%)	0 (0.0%)	1 (1.2%)
Salivary Hypersecretion	0 (0.0%)	4 (4.8%)	0 (0.0%)
Stomach Discomfort	0 (0.0%)	1 (1.2%)	0 (0.0%)
Vomiting	3 (3.5%)	7 (8.3%)	3 (3.6%)
General Disorders And Administration Site Conditions	21 (24.4%)	40 (47.6%)	47 (56.0%)
Application Site Bleeding	0 (0.0%)	0 (0.0%)	1 (1.2%)
Application Site Dermatitis	5 (5.8%)	7 (8.3%)	9 (10.7%)
Application Site Desquamation	0 (0.0%)	0 (0.0%)	1 (1.2%)
Application Site Discharge	0 (0.0%)	1 (1.2%)	0 (0.0%)
Application Site Discolouration	0 (0.0%)	0 (0.0%)	1 (1.2%)

Table 1.0
Summary of Adverse Events
Population: Safety

	Placebo (N=86)	Xanomeline High Dose (N=84)	Xanomeline Low Dose (N=84)
Application Site Erythema	3 (3.5%)	15 (17.9%)	12 (14.3%)
Application Site Induration	1 (1.2%)	0 (0.0%)	0 (0.0%)
Application Site Irritation	3 (3.5%)	9 (10.7%)	9 (10.7%)
Application Site Pain	0 (0.0%)	2 (2.4%)	0 (0.0%)
Application Site Perspiration	0 (0.0%)	2 (2.4%)	0 (0.0%)
Application Site Pruritus	6 (7.0%)	22 (26.2%)	22 (26.2%)
Application Site Reaction	1 (1.2%)	1 (1.2%)	0 (0.0%)
Application Site Swelling	0 (0.0%)	2 (2.4%)	1 (1.2%)
Application Site Urticaria	0 (0.0%)	1 (1.2%)	2 (2.4%)
Application Site Vesicles	1 (1.2%)	6 (7.1%)	4 (4.8%)
Application Site Warmth	0 (0.0%)	0 (0.0%)	1 (1.2%)
Asthenia	1 (1.2%)	1 (1.2%)	0 (0.0%)
Chest Discomfort	0 (0.0%)	2 (2.4%)	0 (0.0%)
Chest Pain	0 (0.0%)	2 (2.4%)	0 (0.0%)
Chills	1 (1.2%)	1 (1.2%)	1 (1.2%)
Cyst	0 (0.0%)	0 (0.0%)	1 (1.2%)
Fatigue	1 (1.2%)	5 (6.0%)	5 (6.0%)
Feeling Abnormal	0 (0.0%)	1 (1.2%)	0 (0.0%)
Feeling Cold	0 (0.0%)	1 (1.2%)	0 (0.0%)
Inflammation	0 (0.0%)	0 (0.0%)	1 (1.2%)
Malaise	0 (0.0%)	2 (2.4%)	1 (1.2%)
Oedema	0 (0.0%)	0 (0.0%)	2 (2.4%)
Oedema Peripheral	2 (2.3%)	2 (2.4%)	1 (1.2%)
Pain	0 (0.0%)	1 (1.2%)	1 (1.2%)
Pyrexia	2 (2.3%)	1 (1.2%)	0 (0.0%)
Secretion Discharge	0 (0.0%)	0 (0.0%)	1 (1.2%)
Sudden Death	0 (0.0%)	0 (0.0%)	1 (1.2%)
Swelling	0 (0.0%)	0 (0.0%)	1 (1.2%)
Ulcer	0 (0.0%)	0 (0.0%)	1 (1.2%)
Hepatobiliary Disorders	1 (1.2%)	0 (0.0%)	0 (0.0%)
Hyperbilirubinaemia	1 (1.2%)	0 (0.0%)	0 (0.0%)

Table 1.0
Summary of Adverse Events
Population: Safety

	Placebo (N=86)	Xanomeline High Dose (N=84)	Xanomeline Low Dose (N=84)
Immune System Disorders	0 (0.0%)	1 (1.2%)	1 (1.2%)
Hypersensitivity	0 (0.0%)	0 (0.0%)	1 (1.2%)
Seasonal Allergy	0 (0.0%)	1 (1.2%)	0 (0.0%)
Infections And Infestations	16 (18.6%)	13 (15.5%)	10 (11.9%)
Bronchitis	1 (1.2%)	0 (0.0%)	0 (0.0%)
Cellulitis	0 (0.0%)	0 (0.0%)	1 (1.2%)
Cervicitis	1 (1.2%)	0 (0.0%)	0 (0.0%)
Cystitis	1 (1.2%)	1 (1.2%)	0 (0.0%)
Ear Infection	2 (2.3%)	0 (0.0%)	0 (0.0%)
Gastroenteritis Viral	1 (1.2%)	0 (0.0%)	0 (0.0%)
Hordeolum	0 (0.0%)	1 (1.2%)	0 (0.0%)
Influenza	1 (1.2%)	1 (1.2%)	1 (1.2%)
Localised Infection	1 (1.2%)	0 (0.0%)	1 (1.2%)
Lower Respiratory Tract Infection	0 (0.0%)	1 (1.2%)	0 (0.0%)
Nasopharyngitis	2 (2.3%)	6 (7.1%)	4 (4.8%)
Onychomycosis	0 (0.0%)	0 (0.0%)	1 (1.2%)
Pneumonia	0 (0.0%)	0 (0.0%)	1 (1.2%)
Rhinitis	0 (0.0%)	1 (1.2%)	0 (0.0%)
Upper Respiratory Tract Infection	6 (7.0%)	3 (3.6%)	1 (1.2%)
Urinary Tract Infection	2 (2.3%)	1 (1.2%)	0 (0.0%)
Vaginal Mycosis	1 (1.2%)	0 (0.0%)	0 (0.0%)
Viral Infection	0 (0.0%)	0 (0.0%)	1 (1.2%)
Injury, Poisoning And Procedural Complications	4 (4.7%)	5 (6.0%)	5 (6.0%)
Contusion	1 (1.2%)	2 (2.4%)	1 (1.2%)
Excoriation	2 (2.3%)	1 (1.2%)	1 (1.2%)
Facial Bones Fracture	0 (0.0%)	1 (1.2%)	0 (0.0%)
Fall	1 (1.2%)	1 (1.2%)	2 (2.4%)
Hip Fracture	1 (1.2%)	2 (2.4%)	0 (0.0%)
Joint Dislocation	0 (0.0%)	0 (0.0%)	1 (1.2%)
Skin Laceration	1 (1.2%)	0 (0.0%)	2 (2.4%)
Wound	0 (0.0%)	0 (0.0%)	1 (1.2%)

Table 1.0
Summary of Adverse Events
Population: Safety

	Placebo (N=86)	Xanomeline High Dose (N=84)	Xanomeline Low Dose (N=84)
Investigations	10 (11.6%)	6 (7.1%)	7 (8.3%)
Biopsy	0 (0.0%)	1 (1.2%)	0 (0.0%)
Biopsy Prostate	0 (0.0%)	1 (1.2%)	0 (0.0%)
Blood Alkaline Phosphatase Increased	1 (1.2%)	0 (0.0%)	0 (0.0%)
Blood Cholesterol Increased	0 (0.0%)	1 (1.2%)	0 (0.0%)
Blood Creatine Phosphokinase Increased	1 (1.2%)	0 (0.0%)	0 (0.0%)
Blood Glucose Increased	0 (0.0%)	1 (1.2%)	1 (1.2%)
Blood Urine Present	1 (1.2%)	0 (0.0%)	0 (0.0%)
Body Temperature Increased	0 (0.0%)	0 (0.0%)	1 (1.2%)
Cystoscopy	1 (1.2%)	0 (0.0%)	0 (0.0%)
Electrocardiogram St Segment Depression	4 (4.7%)	0 (0.0%)	1 (1.2%)
Electrocardiogram T Wave Amplitude Decreased	1 (1.2%)	0 (0.0%)	1 (1.2%)
Electrocardiogram T Wave Inversion	2 (2.3%)	1 (1.2%)	1 (1.2%)
Heart Rate Increased	1 (1.2%)	0 (0.0%)	0 (0.0%)
Heart Rate Irregular	1 (1.2%)	0 (0.0%)	0 (0.0%)
Nasal Mucosa Biopsy	0 (0.0%)	0 (0.0%)	1 (1.2%)
Neutrophil Count Increased	0 (0.0%)	0 (0.0%)	1 (1.2%)
Urine Analysis Abnormal	0 (0.0%)	0 (0.0%)	1 (1.2%)
Weight Decreased	0 (0.0%)	1 (1.2%)	0 (0.0%)
White Blood Cell Count Increased	0 (0.0%)	0 (0.0%)	1 (1.2%)
Metabolism And Nutrition Disorders	6 (7.0%)	3 (3.6%)	1 (1.2%)
Decreased Appetite	1 (1.2%)	1 (1.2%)	0 (0.0%)
Dehydration	1 (1.2%)	0 (0.0%)	0 (0.0%)
Diabetes Mellitus	1 (1.2%)	0 (0.0%)	0 (0.0%)
Food Craving	1 (1.2%)	0 (0.0%)	1 (1.2%)
Hypercholesterolaemia	0 (0.0%)	1 (1.2%)	0 (0.0%)
Hyponatraemia	1 (1.2%)	0 (0.0%)	0 (0.0%)
Increased Appetite	1 (1.2%)	1 (1.2%)	0 (0.0%)
Musculoskeletal And Connective Tissue Disorders	5 (5.8%)	8 (9.5%)	7 (8.3%)
Arthralgia	1 (1.2%)	1 (1.2%)	2 (2.4%)

Table 1.0
Summary of Adverse Events
Population: Safety

	Placebo (N=86)	Xanomeline High Dose (N=84)	Xanomeline Low Dose (N=84)
Arthritis	1 (1.2%)	1 (1.2%)	0 (0.0%)
Back Pain	1 (1.2%)	3 (3.6%)	1 (1.2%)
Flank Pain	0 (0.0%)	2 (2.4%)	0 (0.0%)
Muscle Spasms	0 (0.0%)	1 (1.2%)	1 (1.2%)
Muscular Weakness	0 (0.0%)	0 (0.0%)	1 (1.2%)
Myalgia	0 (0.0%)	1 (1.2%)	0 (0.0%)
Pain In Extremity	1 (1.2%)	0 (0.0%)	0 (0.0%)
Shoulder Pain	1 (1.2%)	0 (0.0%)	2 (2.4%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	0 (0.0%)	1 (1.2%)	2 (2.4%)
Colon Cancer	0 (0.0%)	0 (0.0%)	1 (1.2%)
Malignant Fibrous Histiocytoma	0 (0.0%)	0 (0.0%)	1 (1.2%)
Prostate Cancer	0 (0.0%)	1 (1.2%)	0 (0.0%)
Nervous System Disorders	12 (14.0%)	27 (32.1%)	20 (23.8%)
Amnesia	0 (0.0%)	1 (1.2%)	0 (0.0%)
Balance Disorder	0 (0.0%)	0 (0.0%)	1 (1.2%)
Burning Sensation	0 (0.0%)	2 (2.4%)	0 (0.0%)
Cognitive Disorder	0 (0.0%)	1 (1.2%)	0 (0.0%)
Complex Partial Seizures	0 (0.0%)	0 (0.0%)	1 (1.2%)
Coordination Abnormal	0 (0.0%)	0 (0.0%)	1 (1.2%)
Dizziness	2 (2.3%)	12 (14.3%)	8 (9.5%)
Headache	7 (8.1%)	6 (7.1%)	3 (3.6%)
Hemianopia Homonymous	0 (0.0%)	0 (0.0%)	1 (1.2%)
Hypersomnia	0 (0.0%)	1 (1.2%)	0 (0.0%)
Lethargy	0 (0.0%)	1 (1.2%)	1 (1.2%)
Paraesthesia	0 (0.0%)	1 (1.2%)	0 (0.0%)
Paraesthesia Oral	0 (0.0%)	0 (0.0%)	1 (1.2%)
Parkinson's Disease	1 (1.2%)	0 (0.0%)	0 (0.0%)
Parosmia	0 (0.0%)	1 (1.2%)	0 (0.0%)
Partial Seizures With Secondary Generalisation	0 (0.0%)	1 (1.2%)	0 (0.0%)
Psychomotor Hyperactivity	1 (1.2%)	0 (0.0%)	0 (0.0%)

Table 1.0
Summary of Adverse Events
Population: Safety

	Placebo (N=86)	Xanomeline High Dose (N=84)	Xanomeline Low Dose (N=84)
Somnolence	2 (2.3%)	1 (1.2%)	3 (3.6%)
Stupor	0 (0.0%)	0 (0.0%)	1 (1.2%)
Syncope	0 (0.0%)	3 (3.6%)	4 (4.8%)
Syncope Vasovagal	0 (0.0%)	1 (1.2%)	0 (0.0%)
Transient Ischaemic Attack	0 (0.0%)	1 (1.2%)	2 (2.4%)
Psychiatric Disorders	10 (11.6%)	9 (10.7%)	10 (11.9%)
Agitation	2 (2.3%)	1 (1.2%)	2 (2.4%)
Anxiety	1 (1.2%)	0 (0.0%)	3 (3.6%)
Completed Suicide	1 (1.2%)	0 (0.0%)	0 (0.0%)
Confusional State	2 (2.3%)	1 (1.2%)	3 (3.6%)
Delirium	0 (0.0%)	1 (1.2%)	0 (0.0%)
Delusion	1 (1.2%)	1 (1.2%)	0 (0.0%)
Depressed Mood	0 (0.0%)	1 (1.2%)	1 (1.2%)
Disorientation	1 (1.2%)	0 (0.0%)	0 (0.0%)
Hallucination	0 (0.0%)	1 (1.2%)	0 (0.0%)
Hallucination, Visual	0 (0.0%)	1 (1.2%)	0 (0.0%)
Insomnia	2 (2.3%)	2 (2.4%)	0 (0.0%)
Irritability	1 (1.2%)	0 (0.0%)	1 (1.2%)
Libido Decreased	0 (0.0%)	1 (1.2%)	0 (0.0%)
Listless	0 (0.0%)	1 (1.2%)	0 (0.0%)
Nightmare	0 (0.0%)	1 (1.2%)	0 (0.0%)
Restlessness	0 (0.0%)	0 (0.0%)	1 (1.2%)
Renal And Urinary Disorders	4 (4.7%)	3 (3.6%)	4 (4.8%)
Calculus Urethral	0 (0.0%)	1 (1.2%)	0 (0.0%)
Dysuria	1 (1.2%)	0 (0.0%)	1 (1.2%)
Enuresis	0 (0.0%)	0 (0.0%)	1 (1.2%)
Incontinence	0 (0.0%)	0 (0.0%)	1 (1.2%)
Micturition Urgency	1 (1.2%)	1 (1.2%)	1 (1.2%)
Nephrolithiasis	1 (1.2%)	1 (1.2%)	0 (0.0%)
Pollakiuria	1 (1.2%)	0 (0.0%)	0 (0.0%)

Table 1.0
Summary of Adverse Events
Population: Safety

	Placebo (N=86)	Xanomeline High Dose (N=84)	Xanomeline Low Dose (N=84)
Reproductive System And Breast Disorders	2 (2.3%)	1 (1.2%)	0 (0.0%)
Benign Prostatic Hyperplasia	1 (1.2%)	1 (1.2%)	0 (0.0%)
Pelvic Pain	1 (1.2%)	0 (0.0%)	0 (0.0%)
Respiratory, Thoracic And Mediastinal Disorders	10 (11.6%)	10 (11.9%)	10 (11.9%)
Allergic Granulomatous Angiitis	0 (0.0%)	1 (1.2%)	0 (0.0%)
Cough	3 (3.5%)	5 (6.0%)	6 (7.1%)
Dysphonia	0 (0.0%)	0 (0.0%)	1 (1.2%)
Dyspnoea	1 (1.2%)	1 (1.2%)	1 (1.2%)
Emphysema	1 (1.2%)	0 (0.0%)	0 (0.0%)
Epistaxis	0 (0.0%)	2 (2.4%)	1 (1.2%)
Haemoptysis	1 (1.2%)	0 (0.0%)	0 (0.0%)
Nasal Congestion	3 (3.5%)	3 (3.6%)	1 (1.2%)
Pharyngeal Erythema	0 (0.0%)	1 (1.2%)	0 (0.0%)
Pharyngolaryngeal Pain	0 (0.0%)	1 (1.2%)	1 (1.2%)
Postnasal Drip	1 (1.2%)	0 (0.0%)	0 (0.0%)
Productive Cough	0 (0.0%)	1 (1.2%)	0 (0.0%)
Rales	1 (1.2%)	0 (0.0%)	0 (0.0%)
Respiratory Tract Congestion	0 (0.0%)	1 (1.2%)	0 (0.0%)
Rhinorrhoea	0 (0.0%)	1 (1.2%)	1 (1.2%)
Skin And Subcutaneous Tissue Disorders	21 (24.4%)	42 (50.0%)	42 (50.0%)
Actinic Keratosis	0 (0.0%)	1 (1.2%)	0 (0.0%)
Alopecia	1 (1.2%)	0 (0.0%)	0 (0.0%)
Blister	0 (0.0%)	1 (1.2%)	5 (6.0%)
Cold Sweat	1 (1.2%)	0 (0.0%)	0 (0.0%)
Dermatitis Atopic	1 (1.2%)	0 (0.0%)	0 (0.0%)
Dermatitis Contact	0 (0.0%)	0 (0.0%)	1 (1.2%)
Drug Eruption	1 (1.2%)	0 (0.0%)	0 (0.0%)
Erythema	9 (10.5%)	14 (16.7%)	15 (17.9%)
Hyperhidrosis	2 (2.3%)	8 (9.5%)	4 (4.8%)
Pruritus	8 (9.3%)	26 (31.0%)	23 (27.4%)
Pruritus Generalised	0 (0.0%)	1 (1.2%)	1 (1.2%)

Table 1.0
Summary of Adverse Events
Population: Safety

	Placebo (N=86)	Xanomeline High Dose (N=84)	Xanomeline Low Dose (N=84)
Rash	5 (5.8%)	11 (13.1%)	13 (15.5%)
Rash Erythematous	0 (0.0%)	0 (0.0%)	2 (2.4%)
Rash Maculo-Papular	0 (0.0%)	1 (1.2%)	0 (0.0%)
Rash Papular	0 (0.0%)	1 (1.2%)	0 (0.0%)
Rash Pruritic	0 (0.0%)	2 (2.4%)	1 (1.2%)
Skin Exfoliation	0 (0.0%)	0 (0.0%)	1 (1.2%)
Skin Irritation	3 (3.5%)	5 (6.0%)	6 (7.1%)
Skin Odour Abnormal	0 (0.0%)	1 (1.2%)	0 (0.0%)
Skin Ulcer	1 (1.2%)	0 (0.0%)	0 (0.0%)
Urticaria	0 (0.0%)	1 (1.2%)	1 (1.2%)
Social Circumstances	0 (0.0%)	1 (1.2%)	0 (0.0%)
Alcohol Use	0 (0.0%)	1 (1.2%)	0 (0.0%)
Surgical And Medical Procedures	2 (2.3%)	2 (2.4%)	1 (1.2%)
Acrochordon Excision	0 (0.0%)	1 (1.2%)	0 (0.0%)
Cataract Operation	1 (1.2%)	0 (0.0%)	1 (1.2%)
Eye Laser Surgery	1 (1.2%)	0 (0.0%)	0 (0.0%)
Skin Lesion Excision	0 (0.0%)	1 (1.2%)	0 (0.0%)
Vascular Disorders	3 (3.5%)	2 (2.4%)	3 (3.6%)
Hot Flush	0 (0.0%)	0 (0.0%)	1 (1.2%)
Hypertension	1 (1.2%)	1 (1.2%)	1 (1.2%)
Hypotension	2 (2.3%)	0 (0.0%)	1 (1.2%)
Orthostatic Hypotension	1 (1.2%)	0 (0.0%)	0 (0.0%)
Wound Haemorrhage	0 (0.0%)	1 (1.2%)	0 (0.0%)