Thema 2: Adverse Event Table

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# extract R code from qmd-File  
# knitr::purl("t2\_ae\_tables/t2\_ablauf.qmd", output = "t2\_ae\_tables/t2\_ablauf.R")  
# https://quarto.org/docs/authoring/markdown-basics.html  
  
suppressPackageStartupMessages(library(readr))  
suppressPackageStartupMessages(library(tidyverse))  
suppressPackageStartupMessages(library(ggplot2))  
suppressPackageStartupMessages(library(flextable))  
suppressPackageStartupMessages(library(officer))  
suppressPackageStartupMessages(library(safetyData))

## Beispieldaten für Teil 2 lesen

Im R-Paket **safetyData** sind die Datensätze **sdtm\_ae** und **sdtm\_dm** enthalten.

Diesen lesen wir ein und binden die Therapiearme an den AE-Datensatz an.

#sdtm\_ae <- read\_csv("../data/ae.csv", col\_types = cols(AEENDTC = col\_character()))  
data(sdtm\_ae, package = "safetyData")  
data(sdtm\_dm, package = "safetyData")  
  
ae <- sdtm\_ae  
dm <- sdtm\_dm %>% select(USUBJID, ACTARMCD, ACTARM)  
  
df1 <- left\_join(ae, dm, by = c("USUBJID"))  
df1$TRT <- df1$ACTARMCD  
  
  
# Pbo Xan\_Hi Xan\_Lo   
# 301 436 454

Die absoluten Häufigkeiten werden berechnet.

cnt\_level\_1 <- df1 %>%   
 group\_by(TRT) %>%   
 summarize(cnt\_1 = n()) %>%   
 ungroup()  
  
n\_Pbo <- cnt\_level\_1 %>% filter(TRT == "Pbo") %>% select(cnt\_1) %>% as.integer()  
n\_Xan\_Hi <- cnt\_level\_1 %>% filter(TRT == "Xan\_Hi") %>% select(cnt\_1) %>% as.integer()  
n\_Xan\_Lo <- cnt\_level\_1 %>% filter(TRT == "Xan\_Lo") %>% select(cnt\_1) %>% as.integer()  
  
cl1 <- cnt\_level\_1 %>% pivot\_wider(names\_from = TRT, values\_from = cnt\_1)  
cl1$order <- 1  
cl1$SOC <- "Any Adverse Event"  
cl1$PT <- ""  
cl1 <- cl1 %>% select(SOC, PT, Pbo, Xan\_Hi, Xan\_Lo)  
cl1$Pbo <- paste0(cl1$Pbo, " (100%)")  
cl1$Xan\_Hi <- paste0(cl1$Xan\_Hi, " (100%)")  
cl1$Xan\_Lo <- paste0(cl1$Xan\_Lo, " (100%)")  
  
cnt\_level\_2 <- df1 %>%   
 group\_by(TRT, AEBODSYS) %>%   
 summarize(cnt\_2 = n()) %>%   
 ungroup()

`summarise()` has grouped output by 'TRT'. You can override using the `.groups`  
argument.

cl2 <- cnt\_level\_2 %>% pivot\_wider(names\_from = TRT, values\_from = cnt\_2)  
cl2$order <- 2  
cl2$SOC <- cl2$AEBODSYS  
cl2$PT <- ""  
cl2 <- cl2 %>% select(SOC, PT, Pbo, Xan\_Hi, Xan\_Lo, order)  
  
cnt\_level\_3 <- df1 %>%   
 group\_by(TRT, AEBODSYS, AEDECOD) %>%   
 summarize(cnt\_3 = n()) %>%   
 ungroup()

`summarise()` has grouped output by 'TRT', 'AEBODSYS'. You can override using  
the `.groups` argument.

cl3 <- cnt\_level\_3 %>% pivot\_wider(names\_from = TRT, values\_from = cnt\_3)  
cl3$order <- 3  
cl3$SOC <- cl3$AEBODSYS  
cl3$PT <- cl3$AEDECOD  
cl3 <- cl3 %>% select(SOC, PT, Pbo, Xan\_Hi, Xan\_Lo, order)  
  
ddf <- rbind(cl2, cl3) %>% arrange(SOC, PT)  
df3 <- left\_join(ddf, cl2 %>% select(-c(PT)), by = c("SOC" = "SOC"))  
  
df3$Pbo <- paste0(df3$Pbo.x, " (", round(df3$Pbo.x / df3$Pbo.y \* 100, 1), "%)")  
df3$Pbo <- ifelse(df3$Pbo == "NA (NA%)", "", df3$Pbo)  
  
df3$Xan\_Hi <- paste0(df3$Xan\_Hi.x, " (", round(df3$Xan\_Hi.x / df3$Xan\_Hi.y \* 100, 1), "%)")  
df3$Xan\_Hi <- ifelse(df3$Xan\_Hi == "NA (NA%)", "", df3$Xan\_Hi)  
  
df3$Xan\_Lo <- paste0(df3$Xan\_Lo.x, " (", round(df3$Xan\_Lo.x / df3$Xan\_Lo.y \* 100, 1), "%)")  
df3$Xan\_Lo <- ifelse(df3$Xan\_Lo == "NA (NA%)", "", df3$Xan\_Lo)  
  
df4 <- df3 %>% select(SOC, PT, Pbo, Xan\_Hi, Xan\_Lo)  
df4 <- rbind(cl1, df4)  
  
df4 %>% flextable() %>% autofit()

| SOC | PT | Pbo | Xan\_Hi | Xan\_Lo |
| --- | --- | --- | --- | --- |
| Any Adverse Event |  | 301 (100%) | 436 (100%) | 454 (100%) |
| CARDIAC DISORDERS |  | 27 (100%) | 30 (100%) | 34 (100%) |
| CARDIAC DISORDERS | ATRIAL FIBRILLATION | 1 (3.7%) | 3 (10%) | 3 (8.8%) |
| CARDIAC DISORDERS | ATRIAL FLUTTER |  | 2 (6.7%) | 1 (2.9%) |
| CARDIAC DISORDERS | ATRIAL HYPERTROPHY | 2 (7.4%) |  |  |
| CARDIAC DISORDERS | ATRIOVENTRICULAR BLOCK FIRST DEGREE | 1 (3.7%) |  | 1 (2.9%) |
| CARDIAC DISORDERS | ATRIOVENTRICULAR BLOCK SECOND DEGREE | 2 (7.4%) | 2 (6.7%) | 2 (5.9%) |
| CARDIAC DISORDERS | BRADYCARDIA | 4 (14.8%) |  |  |
| CARDIAC DISORDERS | BUNDLE BRANCH BLOCK LEFT | 1 (3.7%) |  |  |
| CARDIAC DISORDERS | BUNDLE BRANCH BLOCK RIGHT | 2 (7.4%) |  | 1 (2.9%) |
| CARDIAC DISORDERS | CARDIAC DISORDER |  | 1 (3.3%) |  |
| CARDIAC DISORDERS | CARDIAC FAILURE CONGESTIVE | 1 (3.7%) |  |  |
| CARDIAC DISORDERS | MYOCARDIAL INFARCTION | 4 (14.8%) | 8 (26.7%) | 4 (11.8%) |
| CARDIAC DISORDERS | PALPITATIONS |  |  | 2 (5.9%) |
| CARDIAC DISORDERS | SINUS ARRHYTHMIA | 2 (7.4%) |  |  |
| CARDIAC DISORDERS | SINUS BRADYCARDIA | 2 (7.4%) | 12 (40%) | 10 (29.4%) |
| CARDIAC DISORDERS | SUPRAVENTRICULAR EXTRASYSTOLES | 2 (7.4%) | 1 (3.3%) | 2 (5.9%) |
| CARDIAC DISORDERS | SUPRAVENTRICULAR TACHYCARDIA |  |  | 2 (5.9%) |
| CARDIAC DISORDERS | TACHYCARDIA | 2 (7.4%) |  |  |
| CARDIAC DISORDERS | VENTRICULAR EXTRASYSTOLES |  | 1 (3.3%) | 4 (11.8%) |
| CARDIAC DISORDERS | VENTRICULAR HYPERTROPHY | 1 (3.7%) |  |  |
| CARDIAC DISORDERS | WOLFF-PARKINSON-WHITE SYNDROME |  |  | 2 (5.9%) |
| CONGENITAL, FAMILIAL AND GENETIC DISORDERS |  |  | 2 (100%) | 1 (100%) |
| CONGENITAL, FAMILIAL AND GENETIC DISORDERS | VENTRICULAR SEPTAL DEFECT |  | 2 (100%) | 1 (100%) |
| EAR AND LABYRINTH DISORDERS |  | 2 (100%) | 1 (100%) | 3 (100%) |
| EAR AND LABYRINTH DISORDERS | CERUMEN IMPACTION |  |  | 1 (33.3%) |
| EAR AND LABYRINTH DISORDERS | EAR PAIN | 2 (100%) |  |  |
| EAR AND LABYRINTH DISORDERS | TINNITUS |  |  | 1 (33.3%) |
| EAR AND LABYRINTH DISORDERS | VERTIGO |  | 1 (100%) | 1 (33.3%) |
| EYE DISORDERS |  | 8 (100%) | 2 (100%) | 2 (100%) |
| EYE DISORDERS | CONJUNCTIVAL HAEMORRHAGE |  |  | 1 (50%) |
| EYE DISORDERS | CONJUNCTIVITIS | 4 (50%) |  |  |
| EYE DISORDERS | EYE ALLERGY | 1 (12.5%) |  |  |
| EYE DISORDERS | EYE PRURITUS | 1 (12.5%) |  |  |
| EYE DISORDERS | EYE SWELLING | 1 (12.5%) |  |  |
| EYE DISORDERS | GLAUCOMA | 1 (12.5%) |  |  |
| EYE DISORDERS | VISION BLURRED |  | 2 (100%) | 1 (50%) |
| GASTROINTESTINAL DISORDERS |  | 26 (100%) | 35 (100%) | 26 (100%) |
| GASTROINTESTINAL DISORDERS | ABDOMINAL DISCOMFORT |  | 1 (2.9%) |  |
| GASTROINTESTINAL DISORDERS | ABDOMINAL PAIN | 1 (3.8%) | 2 (5.7%) | 3 (11.5%) |
| GASTROINTESTINAL DISORDERS | CONSTIPATION | 1 (3.8%) |  |  |
| GASTROINTESTINAL DISORDERS | DIARRHOEA | 10 (38.5%) | 3 (8.6%) | 8 (30.8%) |
| GASTROINTESTINAL DISORDERS | DYSPEPSIA | 2 (7.7%) | 1 (2.9%) | 2 (7.7%) |
| GASTROINTESTINAL DISORDERS | DYSPHAGIA |  |  | 1 (3.8%) |
| GASTROINTESTINAL DISORDERS | FLATULENCE | 2 (7.7%) |  |  |
| GASTROINTESTINAL DISORDERS | GASTROINTESTINAL HAEMORRHAGE |  | 1 (2.9%) |  |
| GASTROINTESTINAL DISORDERS | GASTROOESOPHAGEAL REFLUX DISEASE | 1 (3.8%) |  |  |
| GASTROINTESTINAL DISORDERS | GLOSSITIS | 1 (3.8%) |  |  |
| GASTROINTESTINAL DISORDERS | HIATUS HERNIA | 2 (7.7%) |  |  |
| GASTROINTESTINAL DISORDERS | NAUSEA | 3 (11.5%) | 13 (37.1%) | 5 (19.2%) |
| GASTROINTESTINAL DISORDERS | RECTAL HAEMORRHAGE |  |  | 2 (7.7%) |
| GASTROINTESTINAL DISORDERS | SALIVARY HYPERSECRETION |  | 5 (14.3%) |  |
| GASTROINTESTINAL DISORDERS | STOMACH DISCOMFORT |  | 1 (2.9%) |  |
| GASTROINTESTINAL DISORDERS | VOMITING | 3 (11.5%) | 8 (22.9%) | 5 (19.2%) |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS |  | 48 (100%) | 118 (100%) | 126 (100%) |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | APPLICATION SITE BLEEDING |  |  | 1 (0.8%) |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | APPLICATION SITE DERMATITIS | 9 (18.8%) | 12 (10.2%) | 15 (11.9%) |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | APPLICATION SITE DESQUAMATION |  |  | 1 (0.8%) |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | APPLICATION SITE DISCHARGE |  | 1 (0.8%) |  |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | APPLICATION SITE DISCOLOURATION |  |  | 1 (0.8%) |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | APPLICATION SITE ERYTHEMA | 3 (6.2%) | 22 (18.6%) | 21 (16.7%) |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | APPLICATION SITE INDURATION | 1 (2.1%) |  |  |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | APPLICATION SITE IRRITATION | 7 (14.6%) | 16 (13.6%) | 18 (14.3%) |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | APPLICATION SITE PAIN |  | 2 (1.7%) |  |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | APPLICATION SITE PERSPIRATION |  | 3 (2.5%) |  |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | APPLICATION SITE PRURITUS | 10 (20.8%) | 34 (28.8%) | 34 (27%) |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | APPLICATION SITE REACTION | 2 (4.2%) | 1 (0.8%) |  |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | APPLICATION SITE SWELLING |  | 3 (2.5%) | 1 (0.8%) |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | APPLICATION SITE URTICARIA |  | 1 (0.8%) | 2 (1.6%) |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | APPLICATION SITE VESICLES | 2 (4.2%) | 5 (4.2%) | 6 (4.8%) |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | APPLICATION SITE WARMTH |  |  | 2 (1.6%) |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | ASTHENIA | 2 (4.2%) |  | 1 (0.8%) |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | CHEST DISCOMFORT |  | 1 (0.8%) | 1 (0.8%) |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | CHEST PAIN |  | 2 (1.7%) |  |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | CHILLS | 3 (6.2%) | 1 (0.8%) | 2 (1.6%) |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | CYST |  |  | 1 (0.8%) |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | FATIGUE | 2 (4.2%) | 5 (4.2%) | 5 (4%) |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | FEELING ABNORMAL |  | 1 (0.8%) |  |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | FEELING COLD |  | 1 (0.8%) |  |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | INFLAMMATION |  |  | 1 (0.8%) |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | MALAISE |  | 3 (2.5%) | 2 (1.6%) |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | OEDEMA |  |  | 2 (1.6%) |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | OEDEMA PERIPHERAL | 5 (10.4%) | 3 (2.5%) | 1 (0.8%) |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | PAIN |  | 1 (0.8%) | 2 (1.6%) |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | PYREXIA | 2 (4.2%) |  | 1 (0.8%) |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | SECRETION DISCHARGE |  |  | 2 (1.6%) |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | SUDDEN DEATH |  |  | 1 (0.8%) |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | SWELLING |  |  | 1 (0.8%) |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | ULCER |  |  | 1 (0.8%) |
| HEPATOBILIARY DISORDERS |  | 1 (100%) |  |  |
| HEPATOBILIARY DISORDERS | HYPERBILIRUBINAEMIA | 1 (100%) |  |  |
| IMMUNE SYSTEM DISORDERS |  |  | 1 (100%) | 2 (100%) |
| IMMUNE SYSTEM DISORDERS | HYPERSENSITIVITY |  |  | 2 (100%) |
| IMMUNE SYSTEM DISORDERS | SEASONAL ALLERGY |  | 1 (100%) |  |
| INFECTIONS AND INFESTATIONS |  | 35 (100%) | 20 (100%) | 18 (100%) |
| INFECTIONS AND INFESTATIONS | BRONCHITIS | 1 (2.9%) |  |  |
| INFECTIONS AND INFESTATIONS | CELLULITIS |  |  | 1 (5.6%) |
| INFECTIONS AND INFESTATIONS | CERVICITIS | 2 (5.7%) |  |  |
| INFECTIONS AND INFESTATIONS | CYSTITIS | 1 (2.9%) | 1 (5%) |  |
| INFECTIONS AND INFESTATIONS | EAR INFECTION | 4 (11.4%) |  |  |
| INFECTIONS AND INFESTATIONS | GASTROENTERITIS VIRAL | 1 (2.9%) |  |  |
| INFECTIONS AND INFESTATIONS | HORDEOLUM |  | 1 (5%) |  |
| INFECTIONS AND INFESTATIONS | INFLUENZA | 2 (5.7%) | 1 (5%) | 1 (5.6%) |
| INFECTIONS AND INFESTATIONS | LOCALISED INFECTION | 2 (5.7%) |  | 1 (5.6%) |
| INFECTIONS AND INFESTATIONS | LOWER RESPIRATORY TRACT INFECTION |  | 2 (10%) |  |
| INFECTIONS AND INFESTATIONS | NASOPHARYNGITIS | 4 (11.4%) | 8 (40%) | 9 (50%) |
| INFECTIONS AND INFESTATIONS | ONYCHOMYCOSIS |  |  | 1 (5.6%) |
| INFECTIONS AND INFESTATIONS | PNEUMONIA |  |  | 2 (11.1%) |
| INFECTIONS AND INFESTATIONS | RHINITIS |  | 1 (5%) |  |
| INFECTIONS AND INFESTATIONS | UPPER RESPIRATORY TRACT INFECTION | 12 (34.3%) | 5 (25%) | 2 (11.1%) |
| INFECTIONS AND INFESTATIONS | URINARY TRACT INFECTION | 4 (11.4%) | 1 (5%) |  |
| INFECTIONS AND INFESTATIONS | VAGINAL MYCOSIS | 2 (5.7%) |  |  |
| INFECTIONS AND INFESTATIONS | VIRAL INFECTION |  |  | 1 (5.6%) |
| INJURY, POISONING AND PROCEDURAL COMPLICATIONS |  | 9 (100%) | 8 (100%) | 12 (100%) |
| INJURY, POISONING AND PROCEDURAL COMPLICATIONS | CONTUSION | 1 (11.1%) | 3 (37.5%) | 3 (25%) |
| INJURY, POISONING AND PROCEDURAL COMPLICATIONS | EXCORIATION | 3 (33.3%) | 1 (12.5%) | 2 (16.7%) |
| INJURY, POISONING AND PROCEDURAL COMPLICATIONS | FACIAL BONES FRACTURE |  | 1 (12.5%) |  |
| INJURY, POISONING AND PROCEDURAL COMPLICATIONS | FALL | 2 (22.2%) | 1 (12.5%) | 2 (16.7%) |
| INJURY, POISONING AND PROCEDURAL COMPLICATIONS | HIP FRACTURE | 2 (22.2%) | 2 (25%) |  |
| INJURY, POISONING AND PROCEDURAL COMPLICATIONS | JOINT DISLOCATION |  |  | 1 (8.3%) |
| INJURY, POISONING AND PROCEDURAL COMPLICATIONS | SKIN LACERATION | 1 (11.1%) |  | 2 (16.7%) |
| INJURY, POISONING AND PROCEDURAL COMPLICATIONS | WOUND |  |  | 2 (16.7%) |
| INVESTIGATIONS |  | 19 (100%) | 6 (100%) | 15 (100%) |
| INVESTIGATIONS | BIOPSY |  | 1 (16.7%) |  |
| INVESTIGATIONS | BIOPSY PROSTATE |  | 1 (16.7%) |  |
| INVESTIGATIONS | BLOOD ALKALINE PHOSPHATASE INCREASED | 1 (5.3%) |  |  |
| INVESTIGATIONS | BLOOD CHOLESTEROL INCREASED |  | 1 (16.7%) |  |
| INVESTIGATIONS | BLOOD CREATINE PHOSPHOKINASE INCREASED | 2 (10.5%) |  |  |
| INVESTIGATIONS | BLOOD GLUCOSE INCREASED |  | 2 (33.3%) | 1 (6.7%) |
| INVESTIGATIONS | BLOOD URINE PRESENT | 1 (5.3%) |  |  |
| INVESTIGATIONS | BODY TEMPERATURE INCREASED |  |  | 1 (6.7%) |
| INVESTIGATIONS | CYSTOSCOPY | 1 (5.3%) |  |  |
| INVESTIGATIONS | ELECTROCARDIOGRAM ST SEGMENT DEPRESSION | 4 (21.1%) |  | 2 (13.3%) |
| INVESTIGATIONS | ELECTROCARDIOGRAM T WAVE AMPLITUDE DECREASED | 1 (5.3%) |  | 1 (6.7%) |
| INVESTIGATIONS | ELECTROCARDIOGRAM T WAVE INVERSION | 3 (15.8%) | 1 (16.7%) | 1 (6.7%) |
| INVESTIGATIONS | HEART RATE INCREASED | 2 (10.5%) |  |  |
| INVESTIGATIONS | HEART RATE IRREGULAR | 4 (21.1%) |  |  |
| INVESTIGATIONS | NASAL MUCOSA BIOPSY |  |  | 1 (6.7%) |
| INVESTIGATIONS | NEUTROPHIL COUNT INCREASED |  |  | 2 (13.3%) |
| INVESTIGATIONS | URINE ANALYSIS ABNORMAL |  |  | 2 (13.3%) |
| INVESTIGATIONS | WEIGHT DECREASED |  |  | 2 (13.3%) |
| INVESTIGATIONS | WHITE BLOOD CELL COUNT INCREASED |  |  | 2 (13.3%) |
| METABOLISM AND NUTRITION DISORDERS |  | 8 (100%) | 5 (100%) | 1 (100%) |
| METABOLISM AND NUTRITION DISORDERS | DECREASED APPETITE | 2 (25%) | 2 (40%) |  |
| METABOLISM AND NUTRITION DISORDERS | DEHYDRATION | 1 (12.5%) |  |  |
| METABOLISM AND NUTRITION DISORDERS | DIABETES MELLITUS | 1 (12.5%) |  |  |
| METABOLISM AND NUTRITION DISORDERS | FOOD CRAVING | 1 (12.5%) |  | 1 (100%) |
| METABOLISM AND NUTRITION DISORDERS | HYPERCHOLESTEROLAEMIA |  | 1 (20%) |  |
| METABOLISM AND NUTRITION DISORDERS | HYPONATRAEMIA | 1 (12.5%) |  |  |
| METABOLISM AND NUTRITION DISORDERS | INCREASED APPETITE | 2 (25%) | 2 (40%) |  |
| MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS |  | 8 (100%) | 11 (100%) | 10 (100%) |
| MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS | ARTHRALGIA | 1 (12.5%) | 1 (9.1%) | 4 (40%) |
| MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS | ARTHRITIS | 2 (25%) | 1 (9.1%) |  |
| MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS | BACK PAIN | 2 (25%) | 4 (36.4%) | 1 (10%) |
| MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS | FLANK PAIN |  | 2 (18.2%) |  |
| MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS | MUSCLE SPASMS |  | 2 (18.2%) | 1 (10%) |
| MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS | MUSCULAR WEAKNESS |  |  | 2 (20%) |
| MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS | MYALGIA |  | 1 (9.1%) |  |
| MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS | PAIN IN EXTREMITY | 1 (12.5%) |  |  |
| MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS | SHOULDER PAIN | 2 (25%) |  | 2 (20%) |
| NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) |  |  | 1 (100%) | 3 (100%) |
| NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) | COLON CANCER |  |  | 1 (33.3%) |
| NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) | MALIGNANT FIBROUS HISTIOCYTOMA |  |  | 2 (66.7%) |
| NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) | PROSTATE CANCER |  | 1 (100%) |  |
| NERVOUS SYSTEM DISORDERS |  | 16 (100%) | 43 (100%) | 42 (100%) |
| NERVOUS SYSTEM DISORDERS | AMNESIA |  | 2 (4.7%) |  |
| NERVOUS SYSTEM DISORDERS | BALANCE DISORDER |  |  | 3 (7.1%) |
| NERVOUS SYSTEM DISORDERS | BURNING SENSATION |  | 2 (4.7%) |  |
| NERVOUS SYSTEM DISORDERS | COGNITIVE DISORDER |  | 1 (2.3%) |  |
| NERVOUS SYSTEM DISORDERS | COMPLEX PARTIAL SEIZURES |  |  | 1 (2.4%) |
| NERVOUS SYSTEM DISORDERS | COORDINATION ABNORMAL |  |  | 1 (2.4%) |
| NERVOUS SYSTEM DISORDERS | DIZZINESS | 3 (18.8%) | 17 (39.5%) | 14 (33.3%) |
| NERVOUS SYSTEM DISORDERS | HEADACHE | 8 (50%) | 9 (20.9%) | 4 (9.5%) |
| NERVOUS SYSTEM DISORDERS | HEMIANOPIA HOMONYMOUS |  |  | 1 (2.4%) |
| NERVOUS SYSTEM DISORDERS | HYPERSOMNIA |  | 1 (2.3%) |  |
| NERVOUS SYSTEM DISORDERS | LETHARGY |  | 1 (2.3%) | 1 (2.4%) |
| NERVOUS SYSTEM DISORDERS | PARAESTHESIA |  | 1 (2.3%) |  |
| NERVOUS SYSTEM DISORDERS | PARAESTHESIA ORAL |  |  | 1 (2.4%) |
| NERVOUS SYSTEM DISORDERS | PARKINSON'S DISEASE | 1 (6.2%) |  |  |
| NERVOUS SYSTEM DISORDERS | PAROSMIA |  | 2 (4.7%) |  |
| NERVOUS SYSTEM DISORDERS | PARTIAL SEIZURES WITH SECONDARY GENERALISATION |  | 1 (2.3%) |  |
| NERVOUS SYSTEM DISORDERS | PSYCHOMOTOR HYPERACTIVITY | 1 (6.2%) |  |  |
| NERVOUS SYSTEM DISORDERS | SOMNOLENCE | 3 (18.8%) | 1 (2.3%) | 5 (11.9%) |
| NERVOUS SYSTEM DISORDERS | STUPOR |  |  | 1 (2.4%) |
| NERVOUS SYSTEM DISORDERS | SYNCOPE |  | 3 (7%) | 7 (16.7%) |
| NERVOUS SYSTEM DISORDERS | SYNCOPE VASOVAGAL |  | 1 (2.3%) |  |
| NERVOUS SYSTEM DISORDERS | TRANSIENT ISCHAEMIC ATTACK |  | 1 (2.3%) | 3 (7.1%) |
| PSYCHIATRIC DISORDERS |  | 14 (100%) | 11 (100%) | 15 (100%) |
| PSYCHIATRIC DISORDERS | AGITATION | 2 (14.3%) |  | 3 (20%) |
| PSYCHIATRIC DISORDERS | ANXIETY | 2 (14.3%) |  | 4 (26.7%) |
| PSYCHIATRIC DISORDERS | COMPLETED SUICIDE | 1 (7.1%) |  |  |
| PSYCHIATRIC DISORDERS | CONFUSIONAL STATE | 2 (14.3%) | 1 (9.1%) | 3 (20%) |
| PSYCHIATRIC DISORDERS | DELIRIUM |  | 1 (9.1%) |  |
| PSYCHIATRIC DISORDERS | DELUSION | 1 (7.1%) | 1 (9.1%) |  |
| PSYCHIATRIC DISORDERS | DEPRESSED MOOD |  | 1 (9.1%) | 2 (13.3%) |
| PSYCHIATRIC DISORDERS | DISORIENTATION | 1 (7.1%) |  |  |
| PSYCHIATRIC DISORDERS | HALLUCINATION |  | 1 (9.1%) |  |
| PSYCHIATRIC DISORDERS | HALLUCINATION, VISUAL |  | 1 (9.1%) |  |
| PSYCHIATRIC DISORDERS | INSOMNIA | 3 (21.4%) | 2 (18.2%) |  |
| PSYCHIATRIC DISORDERS | IRRITABILITY | 2 (14.3%) |  | 1 (6.7%) |
| PSYCHIATRIC DISORDERS | LIBIDO DECREASED |  | 1 (9.1%) |  |
| PSYCHIATRIC DISORDERS | LISTLESS |  | 1 (9.1%) |  |
| PSYCHIATRIC DISORDERS | NIGHTMARE |  | 1 (9.1%) |  |
| PSYCHIATRIC DISORDERS | RESTLESSNESS |  |  | 2 (13.3%) |
| RENAL AND URINARY DISORDERS |  | 5 (100%) | 4 (100%) | 4 (100%) |
| RENAL AND URINARY DISORDERS | CALCULUS URETHRAL |  | 1 (25%) |  |
| RENAL AND URINARY DISORDERS | DYSURIA | 1 (20%) |  | 1 (25%) |
| RENAL AND URINARY DISORDERS | ENURESIS |  |  | 1 (25%) |
| RENAL AND URINARY DISORDERS | INCONTINENCE |  |  | 1 (25%) |
| RENAL AND URINARY DISORDERS | MICTURITION URGENCY | 1 (20%) | 2 (50%) | 1 (25%) |
| RENAL AND URINARY DISORDERS | NEPHROLITHIASIS | 1 (20%) | 1 (25%) |  |
| RENAL AND URINARY DISORDERS | POLLAKIURIA | 2 (40%) |  |  |
| REPRODUCTIVE SYSTEM AND BREAST DISORDERS |  | 4 (100%) | 1 (100%) |  |
| REPRODUCTIVE SYSTEM AND BREAST DISORDERS | BENIGN PROSTATIC HYPERPLASIA | 2 (50%) | 1 (100%) |  |
| REPRODUCTIVE SYSTEM AND BREAST DISORDERS | PELVIC PAIN | 2 (50%) |  |  |
| RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS |  | 15 (100%) | 22 (100%) | 16 (100%) |
| RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS | ALLERGIC GRANULOMATOUS ANGIITIS |  | 1 (4.5%) |  |
| RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS | COUGH | 4 (26.7%) | 7 (31.8%) | 9 (56.2%) |
| RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS | DYSPHONIA |  |  | 1 (6.2%) |
| RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS | DYSPNOEA | 1 (6.7%) | 1 (4.5%) | 1 (6.2%) |
| RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS | EMPHYSEMA | 1 (6.7%) |  |  |
| RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS | EPISTAXIS |  | 2 (9.1%) | 1 (6.2%) |
| RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS | HAEMOPTYSIS | 2 (13.3%) |  |  |
| RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS | NASAL CONGESTION | 3 (20%) | 4 (18.2%) | 1 (6.2%) |
| RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS | PHARYNGEAL ERYTHEMA |  | 2 (9.1%) |  |
| RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS | PHARYNGOLARYNGEAL PAIN |  | 1 (4.5%) | 1 (6.2%) |
| RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS | POSTNASAL DRIP | 2 (13.3%) |  |  |
| RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS | PRODUCTIVE COUGH |  | 1 (4.5%) |  |
| RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS | RALES | 2 (13.3%) |  |  |
| RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS | RESPIRATORY TRACT CONGESTION |  | 1 (4.5%) |  |
| RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS | RHINORRHOEA |  | 2 (9.1%) | 2 (12.5%) |
| SKIN AND SUBCUTANEOUS TISSUE DISORDERS |  | 47 (100%) | 111 (100%) | 118 (100%) |
| SKIN AND SUBCUTANEOUS TISSUE DISORDERS | ACTINIC KERATOSIS |  | 1 (0.9%) |  |
| SKIN AND SUBCUTANEOUS TISSUE DISORDERS | ALOPECIA | 1 (2.1%) |  |  |
| SKIN AND SUBCUTANEOUS TISSUE DISORDERS | BLISTER |  | 2 (1.8%) | 8 (6.8%) |
| SKIN AND SUBCUTANEOUS TISSUE DISORDERS | COLD SWEAT | 3 (6.4%) |  |  |
| SKIN AND SUBCUTANEOUS TISSUE DISORDERS | DERMATITIS ATOPIC | 1 (2.1%) |  |  |
| SKIN AND SUBCUTANEOUS TISSUE DISORDERS | DERMATITIS CONTACT |  |  | 2 (1.7%) |
| SKIN AND SUBCUTANEOUS TISSUE DISORDERS | DRUG ERUPTION | 1 (2.1%) |  |  |
| SKIN AND SUBCUTANEOUS TISSUE DISORDERS | ERYTHEMA | 13 (27.7%) | 22 (19.8%) | 24 (20.3%) |
| SKIN AND SUBCUTANEOUS TISSUE DISORDERS | HYPERHIDROSIS | 2 (4.3%) | 10 (9%) | 5 (4.2%) |
| SKIN AND SUBCUTANEOUS TISSUE DISORDERS | PRURITUS | 11 (23.4%) | 38 (34.2%) | 35 (29.7%) |
| SKIN AND SUBCUTANEOUS TISSUE DISORDERS | PRURITUS GENERALISED |  | 1 (0.9%) | 4 (3.4%) |
| SKIN AND SUBCUTANEOUS TISSUE DISORDERS | RASH | 9 (19.1%) | 18 (16.2%) | 18 (15.3%) |
| SKIN AND SUBCUTANEOUS TISSUE DISORDERS | RASH ERYTHEMATOUS |  |  | 2 (1.7%) |
| SKIN AND SUBCUTANEOUS TISSUE DISORDERS | RASH MACULO-PAPULAR |  | 3 (2.7%) |  |
| SKIN AND SUBCUTANEOUS TISSUE DISORDERS | RASH PAPULAR |  | 2 (1.8%) |  |
| SKIN AND SUBCUTANEOUS TISSUE DISORDERS | RASH PRURITIC |  | 3 (2.7%) | 2 (1.7%) |
| SKIN AND SUBCUTANEOUS TISSUE DISORDERS | SKIN EXFOLIATION |  |  | 2 (1.7%) |
| SKIN AND SUBCUTANEOUS TISSUE DISORDERS | SKIN IRRITATION | 4 (8.5%) | 8 (7.2%) | 13 (11%) |
| SKIN AND SUBCUTANEOUS TISSUE DISORDERS | SKIN ODOUR ABNORMAL |  | 1 (0.9%) |  |
| SKIN AND SUBCUTANEOUS TISSUE DISORDERS | SKIN ULCER | 2 (4.3%) |  |  |
| SKIN AND SUBCUTANEOUS TISSUE DISORDERS | URTICARIA |  | 2 (1.8%) | 3 (2.5%) |
| SOCIAL CIRCUMSTANCES |  |  | 1 (100%) |  |
| SOCIAL CIRCUMSTANCES | ALCOHOL USE |  | 1 (100%) |  |
| SURGICAL AND MEDICAL PROCEDURES |  | 2 (100%) | 2 (100%) | 1 (100%) |
| SURGICAL AND MEDICAL PROCEDURES | ACROCHORDON EXCISION |  | 1 (50%) |  |
| SURGICAL AND MEDICAL PROCEDURES | CATARACT OPERATION | 1 (50%) |  | 1 (100%) |
| SURGICAL AND MEDICAL PROCEDURES | EYE LASER SURGERY | 1 (50%) |  |  |
| SURGICAL AND MEDICAL PROCEDURES | SKIN LESION EXCISION |  | 1 (50%) |  |
| VASCULAR DISORDERS |  | 7 (100%) | 1 (100%) | 5 (100%) |
| VASCULAR DISORDERS | HOT FLUSH |  |  | 1 (20%) |
| VASCULAR DISORDERS | HYPERTENSION | 2 (28.6%) |  | 3 (60%) |
| VASCULAR DISORDERS | HYPOTENSION | 3 (42.9%) |  | 1 (20%) |
| VASCULAR DISORDERS | ORTHOSTATIC HYPOTENSION | 2 (28.6%) |  |  |
| VASCULAR DISORDERS | WOUND HAEMORRHAGE |  | 1 (100%) |  |

SOC und PT lassen sich auch in einer Spalte kombinieren mit eingerücktem PT.

df4$SOC\_PT <- ifelse(df4$PT != "", paste0("\U00A0\U00A0\U00A0", df4$PT), df4$SOC)  
  
ft\_ae <- df4 %>% select(SOC\_PT, Xan\_Hi, Xan\_Lo, Pbo) %>% flextable() %>% autofit()  
ft\_ae

| SOC\_PT | Xan\_Hi | Xan\_Lo | Pbo |
| --- | --- | --- | --- |
| Any Adverse Event | 436 (100%) | 454 (100%) | 301 (100%) |
| CARDIAC DISORDERS | 30 (100%) | 34 (100%) | 27 (100%) |
| ATRIAL FIBRILLATION | 3 (10%) | 3 (8.8%) | 1 (3.7%) |
| ATRIAL FLUTTER | 2 (6.7%) | 1 (2.9%) |  |
| ATRIAL HYPERTROPHY |  |  | 2 (7.4%) |
| ATRIOVENTRICULAR BLOCK FIRST DEGREE |  | 1 (2.9%) | 1 (3.7%) |
| ATRIOVENTRICULAR BLOCK SECOND DEGREE | 2 (6.7%) | 2 (5.9%) | 2 (7.4%) |
| BRADYCARDIA |  |  | 4 (14.8%) |
| BUNDLE BRANCH BLOCK LEFT |  |  | 1 (3.7%) |
| BUNDLE BRANCH BLOCK RIGHT |  | 1 (2.9%) | 2 (7.4%) |
| CARDIAC DISORDER | 1 (3.3%) |  |  |
| CARDIAC FAILURE CONGESTIVE |  |  | 1 (3.7%) |
| MYOCARDIAL INFARCTION | 8 (26.7%) | 4 (11.8%) | 4 (14.8%) |
| PALPITATIONS |  | 2 (5.9%) |  |
| SINUS ARRHYTHMIA |  |  | 2 (7.4%) |
| SINUS BRADYCARDIA | 12 (40%) | 10 (29.4%) | 2 (7.4%) |
| SUPRAVENTRICULAR EXTRASYSTOLES | 1 (3.3%) | 2 (5.9%) | 2 (7.4%) |
| SUPRAVENTRICULAR TACHYCARDIA |  | 2 (5.9%) |  |
| TACHYCARDIA |  |  | 2 (7.4%) |
| VENTRICULAR EXTRASYSTOLES | 1 (3.3%) | 4 (11.8%) |  |
| VENTRICULAR HYPERTROPHY |  |  | 1 (3.7%) |
| WOLFF-PARKINSON-WHITE SYNDROME |  | 2 (5.9%) |  |
| CONGENITAL, FAMILIAL AND GENETIC DISORDERS | 2 (100%) | 1 (100%) |  |
| VENTRICULAR SEPTAL DEFECT | 2 (100%) | 1 (100%) |  |
| EAR AND LABYRINTH DISORDERS | 1 (100%) | 3 (100%) | 2 (100%) |
| CERUMEN IMPACTION |  | 1 (33.3%) |  |
| EAR PAIN |  |  | 2 (100%) |
| TINNITUS |  | 1 (33.3%) |  |
| VERTIGO | 1 (100%) | 1 (33.3%) |  |
| EYE DISORDERS | 2 (100%) | 2 (100%) | 8 (100%) |
| CONJUNCTIVAL HAEMORRHAGE |  | 1 (50%) |  |
| CONJUNCTIVITIS |  |  | 4 (50%) |
| EYE ALLERGY |  |  | 1 (12.5%) |
| EYE PRURITUS |  |  | 1 (12.5%) |
| EYE SWELLING |  |  | 1 (12.5%) |
| GLAUCOMA |  |  | 1 (12.5%) |
| VISION BLURRED | 2 (100%) | 1 (50%) |  |
| GASTROINTESTINAL DISORDERS | 35 (100%) | 26 (100%) | 26 (100%) |
| ABDOMINAL DISCOMFORT | 1 (2.9%) |  |  |
| ABDOMINAL PAIN | 2 (5.7%) | 3 (11.5%) | 1 (3.8%) |
| CONSTIPATION |  |  | 1 (3.8%) |
| DIARRHOEA | 3 (8.6%) | 8 (30.8%) | 10 (38.5%) |
| DYSPEPSIA | 1 (2.9%) | 2 (7.7%) | 2 (7.7%) |
| DYSPHAGIA |  | 1 (3.8%) |  |
| FLATULENCE |  |  | 2 (7.7%) |
| GASTROINTESTINAL HAEMORRHAGE | 1 (2.9%) |  |  |
| GASTROOESOPHAGEAL REFLUX DISEASE |  |  | 1 (3.8%) |
| GLOSSITIS |  |  | 1 (3.8%) |
| HIATUS HERNIA |  |  | 2 (7.7%) |
| NAUSEA | 13 (37.1%) | 5 (19.2%) | 3 (11.5%) |
| RECTAL HAEMORRHAGE |  | 2 (7.7%) |  |
| SALIVARY HYPERSECRETION | 5 (14.3%) |  |  |
| STOMACH DISCOMFORT | 1 (2.9%) |  |  |
| VOMITING | 8 (22.9%) | 5 (19.2%) | 3 (11.5%) |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | 118 (100%) | 126 (100%) | 48 (100%) |
| APPLICATION SITE BLEEDING |  | 1 (0.8%) |  |
| APPLICATION SITE DERMATITIS | 12 (10.2%) | 15 (11.9%) | 9 (18.8%) |
| APPLICATION SITE DESQUAMATION |  | 1 (0.8%) |  |
| APPLICATION SITE DISCHARGE | 1 (0.8%) |  |  |
| APPLICATION SITE DISCOLOURATION |  | 1 (0.8%) |  |
| APPLICATION SITE ERYTHEMA | 22 (18.6%) | 21 (16.7%) | 3 (6.2%) |
| APPLICATION SITE INDURATION |  |  | 1 (2.1%) |
| APPLICATION SITE IRRITATION | 16 (13.6%) | 18 (14.3%) | 7 (14.6%) |
| APPLICATION SITE PAIN | 2 (1.7%) |  |  |
| APPLICATION SITE PERSPIRATION | 3 (2.5%) |  |  |
| APPLICATION SITE PRURITUS | 34 (28.8%) | 34 (27%) | 10 (20.8%) |
| APPLICATION SITE REACTION | 1 (0.8%) |  | 2 (4.2%) |
| APPLICATION SITE SWELLING | 3 (2.5%) | 1 (0.8%) |  |
| APPLICATION SITE URTICARIA | 1 (0.8%) | 2 (1.6%) |  |
| APPLICATION SITE VESICLES | 5 (4.2%) | 6 (4.8%) | 2 (4.2%) |
| APPLICATION SITE WARMTH |  | 2 (1.6%) |  |
| ASTHENIA |  | 1 (0.8%) | 2 (4.2%) |
| CHEST DISCOMFORT | 1 (0.8%) | 1 (0.8%) |  |
| CHEST PAIN | 2 (1.7%) |  |  |
| CHILLS | 1 (0.8%) | 2 (1.6%) | 3 (6.2%) |
| CYST |  | 1 (0.8%) |  |
| FATIGUE | 5 (4.2%) | 5 (4%) | 2 (4.2%) |
| FEELING ABNORMAL | 1 (0.8%) |  |  |
| FEELING COLD | 1 (0.8%) |  |  |
| INFLAMMATION |  | 1 (0.8%) |  |
| MALAISE | 3 (2.5%) | 2 (1.6%) |  |
| OEDEMA |  | 2 (1.6%) |  |
| OEDEMA PERIPHERAL | 3 (2.5%) | 1 (0.8%) | 5 (10.4%) |
| PAIN | 1 (0.8%) | 2 (1.6%) |  |
| PYREXIA |  | 1 (0.8%) | 2 (4.2%) |
| SECRETION DISCHARGE |  | 2 (1.6%) |  |
| SUDDEN DEATH |  | 1 (0.8%) |  |
| SWELLING |  | 1 (0.8%) |  |
| ULCER |  | 1 (0.8%) |  |
| HEPATOBILIARY DISORDERS |  |  | 1 (100%) |
| HYPERBILIRUBINAEMIA |  |  | 1 (100%) |
| IMMUNE SYSTEM DISORDERS | 1 (100%) | 2 (100%) |  |
| HYPERSENSITIVITY |  | 2 (100%) |  |
| SEASONAL ALLERGY | 1 (100%) |  |  |
| INFECTIONS AND INFESTATIONS | 20 (100%) | 18 (100%) | 35 (100%) |
| BRONCHITIS |  |  | 1 (2.9%) |
| CELLULITIS |  | 1 (5.6%) |  |
| CERVICITIS |  |  | 2 (5.7%) |
| CYSTITIS | 1 (5%) |  | 1 (2.9%) |
| EAR INFECTION |  |  | 4 (11.4%) |
| GASTROENTERITIS VIRAL |  |  | 1 (2.9%) |
| HORDEOLUM | 1 (5%) |  |  |
| INFLUENZA | 1 (5%) | 1 (5.6%) | 2 (5.7%) |
| LOCALISED INFECTION |  | 1 (5.6%) | 2 (5.7%) |
| LOWER RESPIRATORY TRACT INFECTION | 2 (10%) |  |  |
| NASOPHARYNGITIS | 8 (40%) | 9 (50%) | 4 (11.4%) |
| ONYCHOMYCOSIS |  | 1 (5.6%) |  |
| PNEUMONIA |  | 2 (11.1%) |  |
| RHINITIS | 1 (5%) |  |  |
| UPPER RESPIRATORY TRACT INFECTION | 5 (25%) | 2 (11.1%) | 12 (34.3%) |
| URINARY TRACT INFECTION | 1 (5%) |  | 4 (11.4%) |
| VAGINAL MYCOSIS |  |  | 2 (5.7%) |
| VIRAL INFECTION |  | 1 (5.6%) |  |
| INJURY, POISONING AND PROCEDURAL COMPLICATIONS | 8 (100%) | 12 (100%) | 9 (100%) |
| CONTUSION | 3 (37.5%) | 3 (25%) | 1 (11.1%) |
| EXCORIATION | 1 (12.5%) | 2 (16.7%) | 3 (33.3%) |
| FACIAL BONES FRACTURE | 1 (12.5%) |  |  |
| FALL | 1 (12.5%) | 2 (16.7%) | 2 (22.2%) |
| HIP FRACTURE | 2 (25%) |  | 2 (22.2%) |
| JOINT DISLOCATION |  | 1 (8.3%) |  |
| SKIN LACERATION |  | 2 (16.7%) | 1 (11.1%) |
| WOUND |  | 2 (16.7%) |  |
| INVESTIGATIONS | 6 (100%) | 15 (100%) | 19 (100%) |
| BIOPSY | 1 (16.7%) |  |  |
| BIOPSY PROSTATE | 1 (16.7%) |  |  |
| BLOOD ALKALINE PHOSPHATASE INCREASED |  |  | 1 (5.3%) |
| BLOOD CHOLESTEROL INCREASED | 1 (16.7%) |  |  |
| BLOOD CREATINE PHOSPHOKINASE INCREASED |  |  | 2 (10.5%) |
| BLOOD GLUCOSE INCREASED | 2 (33.3%) | 1 (6.7%) |  |
| BLOOD URINE PRESENT |  |  | 1 (5.3%) |
| BODY TEMPERATURE INCREASED |  | 1 (6.7%) |  |
| CYSTOSCOPY |  |  | 1 (5.3%) |
| ELECTROCARDIOGRAM ST SEGMENT DEPRESSION |  | 2 (13.3%) | 4 (21.1%) |
| ELECTROCARDIOGRAM T WAVE AMPLITUDE DECREASED |  | 1 (6.7%) | 1 (5.3%) |
| ELECTROCARDIOGRAM T WAVE INVERSION | 1 (16.7%) | 1 (6.7%) | 3 (15.8%) |
| HEART RATE INCREASED |  |  | 2 (10.5%) |
| HEART RATE IRREGULAR |  |  | 4 (21.1%) |
| NASAL MUCOSA BIOPSY |  | 1 (6.7%) |  |
| NEUTROPHIL COUNT INCREASED |  | 2 (13.3%) |  |
| URINE ANALYSIS ABNORMAL |  | 2 (13.3%) |  |
| WEIGHT DECREASED |  | 2 (13.3%) |  |
| WHITE BLOOD CELL COUNT INCREASED |  | 2 (13.3%) |  |
| METABOLISM AND NUTRITION DISORDERS | 5 (100%) | 1 (100%) | 8 (100%) |
| DECREASED APPETITE | 2 (40%) |  | 2 (25%) |
| DEHYDRATION |  |  | 1 (12.5%) |
| DIABETES MELLITUS |  |  | 1 (12.5%) |
| FOOD CRAVING |  | 1 (100%) | 1 (12.5%) |
| HYPERCHOLESTEROLAEMIA | 1 (20%) |  |  |
| HYPONATRAEMIA |  |  | 1 (12.5%) |
| INCREASED APPETITE | 2 (40%) |  | 2 (25%) |
| MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS | 11 (100%) | 10 (100%) | 8 (100%) |
| ARTHRALGIA | 1 (9.1%) | 4 (40%) | 1 (12.5%) |
| ARTHRITIS | 1 (9.1%) |  | 2 (25%) |
| BACK PAIN | 4 (36.4%) | 1 (10%) | 2 (25%) |
| FLANK PAIN | 2 (18.2%) |  |  |
| MUSCLE SPASMS | 2 (18.2%) | 1 (10%) |  |
| MUSCULAR WEAKNESS |  | 2 (20%) |  |
| MYALGIA | 1 (9.1%) |  |  |
| PAIN IN EXTREMITY |  |  | 1 (12.5%) |
| SHOULDER PAIN |  | 2 (20%) | 2 (25%) |
| NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) | 1 (100%) | 3 (100%) |  |
| COLON CANCER |  | 1 (33.3%) |  |
| MALIGNANT FIBROUS HISTIOCYTOMA |  | 2 (66.7%) |  |
| PROSTATE CANCER | 1 (100%) |  |  |
| NERVOUS SYSTEM DISORDERS | 43 (100%) | 42 (100%) | 16 (100%) |
| AMNESIA | 2 (4.7%) |  |  |
| BALANCE DISORDER |  | 3 (7.1%) |  |
| BURNING SENSATION | 2 (4.7%) |  |  |
| COGNITIVE DISORDER | 1 (2.3%) |  |  |
| COMPLEX PARTIAL SEIZURES |  | 1 (2.4%) |  |
| COORDINATION ABNORMAL |  | 1 (2.4%) |  |
| DIZZINESS | 17 (39.5%) | 14 (33.3%) | 3 (18.8%) |
| HEADACHE | 9 (20.9%) | 4 (9.5%) | 8 (50%) |
| HEMIANOPIA HOMONYMOUS |  | 1 (2.4%) |  |
| HYPERSOMNIA | 1 (2.3%) |  |  |
| LETHARGY | 1 (2.3%) | 1 (2.4%) |  |
| PARAESTHESIA | 1 (2.3%) |  |  |
| PARAESTHESIA ORAL |  | 1 (2.4%) |  |
| PARKINSON'S DISEASE |  |  | 1 (6.2%) |
| PAROSMIA | 2 (4.7%) |  |  |
| PARTIAL SEIZURES WITH SECONDARY GENERALISATION | 1 (2.3%) |  |  |
| PSYCHOMOTOR HYPERACTIVITY |  |  | 1 (6.2%) |
| SOMNOLENCE | 1 (2.3%) | 5 (11.9%) | 3 (18.8%) |
| STUPOR |  | 1 (2.4%) |  |
| SYNCOPE | 3 (7%) | 7 (16.7%) |  |
| SYNCOPE VASOVAGAL | 1 (2.3%) |  |  |
| TRANSIENT ISCHAEMIC ATTACK | 1 (2.3%) | 3 (7.1%) |  |
| PSYCHIATRIC DISORDERS | 11 (100%) | 15 (100%) | 14 (100%) |
| AGITATION |  | 3 (20%) | 2 (14.3%) |
| ANXIETY |  | 4 (26.7%) | 2 (14.3%) |
| COMPLETED SUICIDE |  |  | 1 (7.1%) |
| CONFUSIONAL STATE | 1 (9.1%) | 3 (20%) | 2 (14.3%) |
| DELIRIUM | 1 (9.1%) |  |  |
| DELUSION | 1 (9.1%) |  | 1 (7.1%) |
| DEPRESSED MOOD | 1 (9.1%) | 2 (13.3%) |  |
| DISORIENTATION |  |  | 1 (7.1%) |
| HALLUCINATION | 1 (9.1%) |  |  |
| HALLUCINATION, VISUAL | 1 (9.1%) |  |  |
| INSOMNIA | 2 (18.2%) |  | 3 (21.4%) |
| IRRITABILITY |  | 1 (6.7%) | 2 (14.3%) |
| LIBIDO DECREASED | 1 (9.1%) |  |  |
| LISTLESS | 1 (9.1%) |  |  |
| NIGHTMARE | 1 (9.1%) |  |  |
| RESTLESSNESS |  | 2 (13.3%) |  |
| RENAL AND URINARY DISORDERS | 4 (100%) | 4 (100%) | 5 (100%) |
| CALCULUS URETHRAL | 1 (25%) |  |  |
| DYSURIA |  | 1 (25%) | 1 (20%) |
| ENURESIS |  | 1 (25%) |  |
| INCONTINENCE |  | 1 (25%) |  |
| MICTURITION URGENCY | 2 (50%) | 1 (25%) | 1 (20%) |
| NEPHROLITHIASIS | 1 (25%) |  | 1 (20%) |
| POLLAKIURIA |  |  | 2 (40%) |
| REPRODUCTIVE SYSTEM AND BREAST DISORDERS | 1 (100%) |  | 4 (100%) |
| BENIGN PROSTATIC HYPERPLASIA | 1 (100%) |  | 2 (50%) |
| PELVIC PAIN |  |  | 2 (50%) |
| RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS | 22 (100%) | 16 (100%) | 15 (100%) |
| ALLERGIC GRANULOMATOUS ANGIITIS | 1 (4.5%) |  |  |
| COUGH | 7 (31.8%) | 9 (56.2%) | 4 (26.7%) |
| DYSPHONIA |  | 1 (6.2%) |  |
| DYSPNOEA | 1 (4.5%) | 1 (6.2%) | 1 (6.7%) |
| EMPHYSEMA |  |  | 1 (6.7%) |
| EPISTAXIS | 2 (9.1%) | 1 (6.2%) |  |
| HAEMOPTYSIS |  |  | 2 (13.3%) |
| NASAL CONGESTION | 4 (18.2%) | 1 (6.2%) | 3 (20%) |
| PHARYNGEAL ERYTHEMA | 2 (9.1%) |  |  |
| PHARYNGOLARYNGEAL PAIN | 1 (4.5%) | 1 (6.2%) |  |
| POSTNASAL DRIP |  |  | 2 (13.3%) |
| PRODUCTIVE COUGH | 1 (4.5%) |  |  |
| RALES |  |  | 2 (13.3%) |
| RESPIRATORY TRACT CONGESTION | 1 (4.5%) |  |  |
| RHINORRHOEA | 2 (9.1%) | 2 (12.5%) |  |
| SKIN AND SUBCUTANEOUS TISSUE DISORDERS | 111 (100%) | 118 (100%) | 47 (100%) |
| ACTINIC KERATOSIS | 1 (0.9%) |  |  |
| ALOPECIA |  |  | 1 (2.1%) |
| BLISTER | 2 (1.8%) | 8 (6.8%) |  |
| COLD SWEAT |  |  | 3 (6.4%) |
| DERMATITIS ATOPIC |  |  | 1 (2.1%) |
| DERMATITIS CONTACT |  | 2 (1.7%) |  |
| DRUG ERUPTION |  |  | 1 (2.1%) |
| ERYTHEMA | 22 (19.8%) | 24 (20.3%) | 13 (27.7%) |
| HYPERHIDROSIS | 10 (9%) | 5 (4.2%) | 2 (4.3%) |
| PRURITUS | 38 (34.2%) | 35 (29.7%) | 11 (23.4%) |
| PRURITUS GENERALISED | 1 (0.9%) | 4 (3.4%) |  |
| RASH | 18 (16.2%) | 18 (15.3%) | 9 (19.1%) |
| RASH ERYTHEMATOUS |  | 2 (1.7%) |  |
| RASH MACULO-PAPULAR | 3 (2.7%) |  |  |
| RASH PAPULAR | 2 (1.8%) |  |  |
| RASH PRURITIC | 3 (2.7%) | 2 (1.7%) |  |
| SKIN EXFOLIATION |  | 2 (1.7%) |  |
| SKIN IRRITATION | 8 (7.2%) | 13 (11%) | 4 (8.5%) |
| SKIN ODOUR ABNORMAL | 1 (0.9%) |  |  |
| SKIN ULCER |  |  | 2 (4.3%) |
| URTICARIA | 2 (1.8%) | 3 (2.5%) |  |
| SOCIAL CIRCUMSTANCES | 1 (100%) |  |  |
| ALCOHOL USE | 1 (100%) |  |  |
| SURGICAL AND MEDICAL PROCEDURES | 2 (100%) | 1 (100%) | 2 (100%) |
| ACROCHORDON EXCISION | 1 (50%) |  |  |
| CATARACT OPERATION |  | 1 (100%) | 1 (50%) |
| EYE LASER SURGERY |  |  | 1 (50%) |
| SKIN LESION EXCISION | 1 (50%) |  |  |
| VASCULAR DISORDERS | 1 (100%) | 5 (100%) | 7 (100%) |
| HOT FLUSH |  | 1 (20%) |  |
| HYPERTENSION |  | 3 (60%) | 2 (28.6%) |
| HYPOTENSION |  | 1 (20%) | 3 (42.9%) |
| ORTHOSTATIC HYPOTENSION |  |  | 2 (28.6%) |
| WOUND HAEMORRHAGE | 1 (100%) |  |  |

Jetzt werden noch die Feinheiten wie bei der Table 1 ergänzt.

my\_border = fp\_border(color="black", width = 2)  
  
ft\_ae <- ft\_ae %>%   
 add\_header\_lines(c("Study title", "1.2.3 Summary of Adverse Events", "SAF")) %>%  
 add\_footer\_lines(c("Abbreviations and comments", "Program name / Run date / Data cut date")) %>%  
 border\_remove() %>%   
 set\_header\_labels(  
 Label = "",  
 SOC\_PT = "System Organ Class\n\U00A0\U00A0\U00A0Preferred Term",   
 Xan\_Hi = paste0("Xan High\n(n = ", n\_Xan\_Hi, ")"),  
 Xan\_Lo = paste0("Xan Low\n(n = ", n\_Xan\_Lo, ")"),  
 Pbo = paste0("Placebo\n(n = ", n\_Pbo, ")")  
) %>%  
 hline\_top(border = my\_border, part = "footer") %>%  
 hline\_bottom(border = my\_border, part = "header") %>%  
 hline\_bottom(border = my\_border, part = "body") %>%  
 hline(i = c(3), border = my\_border, part = "header") %>%  
 align(j = c(2, 3, 4), align = "right", part = "header") %>%  
 align(j = c(2, 3, 4), align = "right", part = "body")  
ft\_ae

| Study title | | | |
| --- | --- | --- | --- |
| 1.2.3 Summary of Adverse Events | | | |
| SAF | | | |
| System Organ Class    Preferred Term | Xan High (n = 436) | Xan Low (n = 454) | Placebo (n = 301) |
| Any Adverse Event | 436 (100%) | 454 (100%) | 301 (100%) |
| CARDIAC DISORDERS | 30 (100%) | 34 (100%) | 27 (100%) |
| ATRIAL FIBRILLATION | 3 (10%) | 3 (8.8%) | 1 (3.7%) |
| ATRIAL FLUTTER | 2 (6.7%) | 1 (2.9%) |  |
| ATRIAL HYPERTROPHY |  |  | 2 (7.4%) |
| ATRIOVENTRICULAR BLOCK FIRST DEGREE |  | 1 (2.9%) | 1 (3.7%) |
| ATRIOVENTRICULAR BLOCK SECOND DEGREE | 2 (6.7%) | 2 (5.9%) | 2 (7.4%) |
| BRADYCARDIA |  |  | 4 (14.8%) |
| BUNDLE BRANCH BLOCK LEFT |  |  | 1 (3.7%) |
| BUNDLE BRANCH BLOCK RIGHT |  | 1 (2.9%) | 2 (7.4%) |
| CARDIAC DISORDER | 1 (3.3%) |  |  |
| CARDIAC FAILURE CONGESTIVE |  |  | 1 (3.7%) |
| MYOCARDIAL INFARCTION | 8 (26.7%) | 4 (11.8%) | 4 (14.8%) |
| PALPITATIONS |  | 2 (5.9%) |  |
| SINUS ARRHYTHMIA |  |  | 2 (7.4%) |
| SINUS BRADYCARDIA | 12 (40%) | 10 (29.4%) | 2 (7.4%) |
| SUPRAVENTRICULAR EXTRASYSTOLES | 1 (3.3%) | 2 (5.9%) | 2 (7.4%) |
| SUPRAVENTRICULAR TACHYCARDIA |  | 2 (5.9%) |  |
| TACHYCARDIA |  |  | 2 (7.4%) |
| VENTRICULAR EXTRASYSTOLES | 1 (3.3%) | 4 (11.8%) |  |
| VENTRICULAR HYPERTROPHY |  |  | 1 (3.7%) |
| WOLFF-PARKINSON-WHITE SYNDROME |  | 2 (5.9%) |  |
| CONGENITAL, FAMILIAL AND GENETIC DISORDERS | 2 (100%) | 1 (100%) |  |
| VENTRICULAR SEPTAL DEFECT | 2 (100%) | 1 (100%) |  |
| EAR AND LABYRINTH DISORDERS | 1 (100%) | 3 (100%) | 2 (100%) |
| CERUMEN IMPACTION |  | 1 (33.3%) |  |
| EAR PAIN |  |  | 2 (100%) |
| TINNITUS |  | 1 (33.3%) |  |
| VERTIGO | 1 (100%) | 1 (33.3%) |  |
| EYE DISORDERS | 2 (100%) | 2 (100%) | 8 (100%) |
| CONJUNCTIVAL HAEMORRHAGE |  | 1 (50%) |  |
| CONJUNCTIVITIS |  |  | 4 (50%) |
| EYE ALLERGY |  |  | 1 (12.5%) |
| EYE PRURITUS |  |  | 1 (12.5%) |
| EYE SWELLING |  |  | 1 (12.5%) |
| GLAUCOMA |  |  | 1 (12.5%) |
| VISION BLURRED | 2 (100%) | 1 (50%) |  |
| GASTROINTESTINAL DISORDERS | 35 (100%) | 26 (100%) | 26 (100%) |
| ABDOMINAL DISCOMFORT | 1 (2.9%) |  |  |
| ABDOMINAL PAIN | 2 (5.7%) | 3 (11.5%) | 1 (3.8%) |
| CONSTIPATION |  |  | 1 (3.8%) |
| DIARRHOEA | 3 (8.6%) | 8 (30.8%) | 10 (38.5%) |
| DYSPEPSIA | 1 (2.9%) | 2 (7.7%) | 2 (7.7%) |
| DYSPHAGIA |  | 1 (3.8%) |  |
| FLATULENCE |  |  | 2 (7.7%) |
| GASTROINTESTINAL HAEMORRHAGE | 1 (2.9%) |  |  |
| GASTROOESOPHAGEAL REFLUX DISEASE |  |  | 1 (3.8%) |
| GLOSSITIS |  |  | 1 (3.8%) |
| HIATUS HERNIA |  |  | 2 (7.7%) |
| NAUSEA | 13 (37.1%) | 5 (19.2%) | 3 (11.5%) |
| RECTAL HAEMORRHAGE |  | 2 (7.7%) |  |
| SALIVARY HYPERSECRETION | 5 (14.3%) |  |  |
| STOMACH DISCOMFORT | 1 (2.9%) |  |  |
| VOMITING | 8 (22.9%) | 5 (19.2%) | 3 (11.5%) |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | 118 (100%) | 126 (100%) | 48 (100%) |
| APPLICATION SITE BLEEDING |  | 1 (0.8%) |  |
| APPLICATION SITE DERMATITIS | 12 (10.2%) | 15 (11.9%) | 9 (18.8%) |
| APPLICATION SITE DESQUAMATION |  | 1 (0.8%) |  |
| APPLICATION SITE DISCHARGE | 1 (0.8%) |  |  |
| APPLICATION SITE DISCOLOURATION |  | 1 (0.8%) |  |
| APPLICATION SITE ERYTHEMA | 22 (18.6%) | 21 (16.7%) | 3 (6.2%) |
| APPLICATION SITE INDURATION |  |  | 1 (2.1%) |
| APPLICATION SITE IRRITATION | 16 (13.6%) | 18 (14.3%) | 7 (14.6%) |
| APPLICATION SITE PAIN | 2 (1.7%) |  |  |
| APPLICATION SITE PERSPIRATION | 3 (2.5%) |  |  |
| APPLICATION SITE PRURITUS | 34 (28.8%) | 34 (27%) | 10 (20.8%) |
| APPLICATION SITE REACTION | 1 (0.8%) |  | 2 (4.2%) |
| APPLICATION SITE SWELLING | 3 (2.5%) | 1 (0.8%) |  |
| APPLICATION SITE URTICARIA | 1 (0.8%) | 2 (1.6%) |  |
| APPLICATION SITE VESICLES | 5 (4.2%) | 6 (4.8%) | 2 (4.2%) |
| APPLICATION SITE WARMTH |  | 2 (1.6%) |  |
| ASTHENIA |  | 1 (0.8%) | 2 (4.2%) |
| CHEST DISCOMFORT | 1 (0.8%) | 1 (0.8%) |  |
| CHEST PAIN | 2 (1.7%) |  |  |
| CHILLS | 1 (0.8%) | 2 (1.6%) | 3 (6.2%) |
| CYST |  | 1 (0.8%) |  |
| FATIGUE | 5 (4.2%) | 5 (4%) | 2 (4.2%) |
| FEELING ABNORMAL | 1 (0.8%) |  |  |
| FEELING COLD | 1 (0.8%) |  |  |
| INFLAMMATION |  | 1 (0.8%) |  |
| MALAISE | 3 (2.5%) | 2 (1.6%) |  |
| OEDEMA |  | 2 (1.6%) |  |
| OEDEMA PERIPHERAL | 3 (2.5%) | 1 (0.8%) | 5 (10.4%) |
| PAIN | 1 (0.8%) | 2 (1.6%) |  |
| PYREXIA |  | 1 (0.8%) | 2 (4.2%) |
| SECRETION DISCHARGE |  | 2 (1.6%) |  |
| SUDDEN DEATH |  | 1 (0.8%) |  |
| SWELLING |  | 1 (0.8%) |  |
| ULCER |  | 1 (0.8%) |  |
| HEPATOBILIARY DISORDERS |  |  | 1 (100%) |
| HYPERBILIRUBINAEMIA |  |  | 1 (100%) |
| IMMUNE SYSTEM DISORDERS | 1 (100%) | 2 (100%) |  |
| HYPERSENSITIVITY |  | 2 (100%) |  |
| SEASONAL ALLERGY | 1 (100%) |  |  |
| INFECTIONS AND INFESTATIONS | 20 (100%) | 18 (100%) | 35 (100%) |
| BRONCHITIS |  |  | 1 (2.9%) |
| CELLULITIS |  | 1 (5.6%) |  |
| CERVICITIS |  |  | 2 (5.7%) |
| CYSTITIS | 1 (5%) |  | 1 (2.9%) |
| EAR INFECTION |  |  | 4 (11.4%) |
| GASTROENTERITIS VIRAL |  |  | 1 (2.9%) |
| HORDEOLUM | 1 (5%) |  |  |
| INFLUENZA | 1 (5%) | 1 (5.6%) | 2 (5.7%) |
| LOCALISED INFECTION |  | 1 (5.6%) | 2 (5.7%) |
| LOWER RESPIRATORY TRACT INFECTION | 2 (10%) |  |  |
| NASOPHARYNGITIS | 8 (40%) | 9 (50%) | 4 (11.4%) |
| ONYCHOMYCOSIS |  | 1 (5.6%) |  |
| PNEUMONIA |  | 2 (11.1%) |  |
| RHINITIS | 1 (5%) |  |  |
| UPPER RESPIRATORY TRACT INFECTION | 5 (25%) | 2 (11.1%) | 12 (34.3%) |
| URINARY TRACT INFECTION | 1 (5%) |  | 4 (11.4%) |
| VAGINAL MYCOSIS |  |  | 2 (5.7%) |
| VIRAL INFECTION |  | 1 (5.6%) |  |
| INJURY, POISONING AND PROCEDURAL COMPLICATIONS | 8 (100%) | 12 (100%) | 9 (100%) |
| CONTUSION | 3 (37.5%) | 3 (25%) | 1 (11.1%) |
| EXCORIATION | 1 (12.5%) | 2 (16.7%) | 3 (33.3%) |
| FACIAL BONES FRACTURE | 1 (12.5%) |  |  |
| FALL | 1 (12.5%) | 2 (16.7%) | 2 (22.2%) |
| HIP FRACTURE | 2 (25%) |  | 2 (22.2%) |
| JOINT DISLOCATION |  | 1 (8.3%) |  |
| SKIN LACERATION |  | 2 (16.7%) | 1 (11.1%) |
| WOUND |  | 2 (16.7%) |  |
| INVESTIGATIONS | 6 (100%) | 15 (100%) | 19 (100%) |
| BIOPSY | 1 (16.7%) |  |  |
| BIOPSY PROSTATE | 1 (16.7%) |  |  |
| BLOOD ALKALINE PHOSPHATASE INCREASED |  |  | 1 (5.3%) |
| BLOOD CHOLESTEROL INCREASED | 1 (16.7%) |  |  |
| BLOOD CREATINE PHOSPHOKINASE INCREASED |  |  | 2 (10.5%) |
| BLOOD GLUCOSE INCREASED | 2 (33.3%) | 1 (6.7%) |  |
| BLOOD URINE PRESENT |  |  | 1 (5.3%) |
| BODY TEMPERATURE INCREASED |  | 1 (6.7%) |  |
| CYSTOSCOPY |  |  | 1 (5.3%) |
| ELECTROCARDIOGRAM ST SEGMENT DEPRESSION |  | 2 (13.3%) | 4 (21.1%) |
| ELECTROCARDIOGRAM T WAVE AMPLITUDE DECREASED |  | 1 (6.7%) | 1 (5.3%) |
| ELECTROCARDIOGRAM T WAVE INVERSION | 1 (16.7%) | 1 (6.7%) | 3 (15.8%) |
| HEART RATE INCREASED |  |  | 2 (10.5%) |
| HEART RATE IRREGULAR |  |  | 4 (21.1%) |
| NASAL MUCOSA BIOPSY |  | 1 (6.7%) |  |
| NEUTROPHIL COUNT INCREASED |  | 2 (13.3%) |  |
| URINE ANALYSIS ABNORMAL |  | 2 (13.3%) |  |
| WEIGHT DECREASED |  | 2 (13.3%) |  |
| WHITE BLOOD CELL COUNT INCREASED |  | 2 (13.3%) |  |
| METABOLISM AND NUTRITION DISORDERS | 5 (100%) | 1 (100%) | 8 (100%) |
| DECREASED APPETITE | 2 (40%) |  | 2 (25%) |
| DEHYDRATION |  |  | 1 (12.5%) |
| DIABETES MELLITUS |  |  | 1 (12.5%) |
| FOOD CRAVING |  | 1 (100%) | 1 (12.5%) |
| HYPERCHOLESTEROLAEMIA | 1 (20%) |  |  |
| HYPONATRAEMIA |  |  | 1 (12.5%) |
| INCREASED APPETITE | 2 (40%) |  | 2 (25%) |
| MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS | 11 (100%) | 10 (100%) | 8 (100%) |
| ARTHRALGIA | 1 (9.1%) | 4 (40%) | 1 (12.5%) |
| ARTHRITIS | 1 (9.1%) |  | 2 (25%) |
| BACK PAIN | 4 (36.4%) | 1 (10%) | 2 (25%) |
| FLANK PAIN | 2 (18.2%) |  |  |
| MUSCLE SPASMS | 2 (18.2%) | 1 (10%) |  |
| MUSCULAR WEAKNESS |  | 2 (20%) |  |
| MYALGIA | 1 (9.1%) |  |  |
| PAIN IN EXTREMITY |  |  | 1 (12.5%) |
| SHOULDER PAIN |  | 2 (20%) | 2 (25%) |
| NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) | 1 (100%) | 3 (100%) |  |
| COLON CANCER |  | 1 (33.3%) |  |
| MALIGNANT FIBROUS HISTIOCYTOMA |  | 2 (66.7%) |  |
| PROSTATE CANCER | 1 (100%) |  |  |
| NERVOUS SYSTEM DISORDERS | 43 (100%) | 42 (100%) | 16 (100%) |
| AMNESIA | 2 (4.7%) |  |  |
| BALANCE DISORDER |  | 3 (7.1%) |  |
| BURNING SENSATION | 2 (4.7%) |  |  |
| COGNITIVE DISORDER | 1 (2.3%) |  |  |
| COMPLEX PARTIAL SEIZURES |  | 1 (2.4%) |  |
| COORDINATION ABNORMAL |  | 1 (2.4%) |  |
| DIZZINESS | 17 (39.5%) | 14 (33.3%) | 3 (18.8%) |
| HEADACHE | 9 (20.9%) | 4 (9.5%) | 8 (50%) |
| HEMIANOPIA HOMONYMOUS |  | 1 (2.4%) |  |
| HYPERSOMNIA | 1 (2.3%) |  |  |
| LETHARGY | 1 (2.3%) | 1 (2.4%) |  |
| PARAESTHESIA | 1 (2.3%) |  |  |
| PARAESTHESIA ORAL |  | 1 (2.4%) |  |
| PARKINSON'S DISEASE |  |  | 1 (6.2%) |
| PAROSMIA | 2 (4.7%) |  |  |
| PARTIAL SEIZURES WITH SECONDARY GENERALISATION | 1 (2.3%) |  |  |
| PSYCHOMOTOR HYPERACTIVITY |  |  | 1 (6.2%) |
| SOMNOLENCE | 1 (2.3%) | 5 (11.9%) | 3 (18.8%) |
| STUPOR |  | 1 (2.4%) |  |
| SYNCOPE | 3 (7%) | 7 (16.7%) |  |
| SYNCOPE VASOVAGAL | 1 (2.3%) |  |  |
| TRANSIENT ISCHAEMIC ATTACK | 1 (2.3%) | 3 (7.1%) |  |
| PSYCHIATRIC DISORDERS | 11 (100%) | 15 (100%) | 14 (100%) |
| AGITATION |  | 3 (20%) | 2 (14.3%) |
| ANXIETY |  | 4 (26.7%) | 2 (14.3%) |
| COMPLETED SUICIDE |  |  | 1 (7.1%) |
| CONFUSIONAL STATE | 1 (9.1%) | 3 (20%) | 2 (14.3%) |
| DELIRIUM | 1 (9.1%) |  |  |
| DELUSION | 1 (9.1%) |  | 1 (7.1%) |
| DEPRESSED MOOD | 1 (9.1%) | 2 (13.3%) |  |
| DISORIENTATION |  |  | 1 (7.1%) |
| HALLUCINATION | 1 (9.1%) |  |  |
| HALLUCINATION, VISUAL | 1 (9.1%) |  |  |
| INSOMNIA | 2 (18.2%) |  | 3 (21.4%) |
| IRRITABILITY |  | 1 (6.7%) | 2 (14.3%) |
| LIBIDO DECREASED | 1 (9.1%) |  |  |
| LISTLESS | 1 (9.1%) |  |  |
| NIGHTMARE | 1 (9.1%) |  |  |
| RESTLESSNESS |  | 2 (13.3%) |  |
| RENAL AND URINARY DISORDERS | 4 (100%) | 4 (100%) | 5 (100%) |
| CALCULUS URETHRAL | 1 (25%) |  |  |
| DYSURIA |  | 1 (25%) | 1 (20%) |
| ENURESIS |  | 1 (25%) |  |
| INCONTINENCE |  | 1 (25%) |  |
| MICTURITION URGENCY | 2 (50%) | 1 (25%) | 1 (20%) |
| NEPHROLITHIASIS | 1 (25%) |  | 1 (20%) |
| POLLAKIURIA |  |  | 2 (40%) |
| REPRODUCTIVE SYSTEM AND BREAST DISORDERS | 1 (100%) |  | 4 (100%) |
| BENIGN PROSTATIC HYPERPLASIA | 1 (100%) |  | 2 (50%) |
| PELVIC PAIN |  |  | 2 (50%) |
| RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS | 22 (100%) | 16 (100%) | 15 (100%) |
| ALLERGIC GRANULOMATOUS ANGIITIS | 1 (4.5%) |  |  |
| COUGH | 7 (31.8%) | 9 (56.2%) | 4 (26.7%) |
| DYSPHONIA |  | 1 (6.2%) |  |
| DYSPNOEA | 1 (4.5%) | 1 (6.2%) | 1 (6.7%) |
| EMPHYSEMA |  |  | 1 (6.7%) |
| EPISTAXIS | 2 (9.1%) | 1 (6.2%) |  |
| HAEMOPTYSIS |  |  | 2 (13.3%) |
| NASAL CONGESTION | 4 (18.2%) | 1 (6.2%) | 3 (20%) |
| PHARYNGEAL ERYTHEMA | 2 (9.1%) |  |  |
| PHARYNGOLARYNGEAL PAIN | 1 (4.5%) | 1 (6.2%) |  |
| POSTNASAL DRIP |  |  | 2 (13.3%) |
| PRODUCTIVE COUGH | 1 (4.5%) |  |  |
| RALES |  |  | 2 (13.3%) |
| RESPIRATORY TRACT CONGESTION | 1 (4.5%) |  |  |
| RHINORRHOEA | 2 (9.1%) | 2 (12.5%) |  |
| SKIN AND SUBCUTANEOUS TISSUE DISORDERS | 111 (100%) | 118 (100%) | 47 (100%) |
| ACTINIC KERATOSIS | 1 (0.9%) |  |  |
| ALOPECIA |  |  | 1 (2.1%) |
| BLISTER | 2 (1.8%) | 8 (6.8%) |  |
| COLD SWEAT |  |  | 3 (6.4%) |
| DERMATITIS ATOPIC |  |  | 1 (2.1%) |
| DERMATITIS CONTACT |  | 2 (1.7%) |  |
| DRUG ERUPTION |  |  | 1 (2.1%) |
| ERYTHEMA | 22 (19.8%) | 24 (20.3%) | 13 (27.7%) |
| HYPERHIDROSIS | 10 (9%) | 5 (4.2%) | 2 (4.3%) |
| PRURITUS | 38 (34.2%) | 35 (29.7%) | 11 (23.4%) |
| PRURITUS GENERALISED | 1 (0.9%) | 4 (3.4%) |  |
| RASH | 18 (16.2%) | 18 (15.3%) | 9 (19.1%) |
| RASH ERYTHEMATOUS |  | 2 (1.7%) |  |
| RASH MACULO-PAPULAR | 3 (2.7%) |  |  |
| RASH PAPULAR | 2 (1.8%) |  |  |
| RASH PRURITIC | 3 (2.7%) | 2 (1.7%) |  |
| SKIN EXFOLIATION |  | 2 (1.7%) |  |
| SKIN IRRITATION | 8 (7.2%) | 13 (11%) | 4 (8.5%) |
| SKIN ODOUR ABNORMAL | 1 (0.9%) |  |  |
| SKIN ULCER |  |  | 2 (4.3%) |
| URTICARIA | 2 (1.8%) | 3 (2.5%) |  |
| SOCIAL CIRCUMSTANCES | 1 (100%) |  |  |
| ALCOHOL USE | 1 (100%) |  |  |
| SURGICAL AND MEDICAL PROCEDURES | 2 (100%) | 1 (100%) | 2 (100%) |
| ACROCHORDON EXCISION | 1 (50%) |  |  |
| CATARACT OPERATION |  | 1 (100%) | 1 (50%) |
| EYE LASER SURGERY |  |  | 1 (50%) |
| SKIN LESION EXCISION | 1 (50%) |  |  |
| VASCULAR DISORDERS | 1 (100%) | 5 (100%) | 7 (100%) |
| HOT FLUSH |  | 1 (20%) |  |
| HYPERTENSION |  | 3 (60%) | 2 (28.6%) |
| HYPOTENSION |  | 1 (20%) | 3 (42.9%) |
| ORTHOSTATIC HYPOTENSION |  |  | 2 (28.6%) |
| WOUND HAEMORRHAGE | 1 (100%) |  |  |
| Abbreviations and comments | | | |
| Program name / Run date / Data cut date | | | |

## Abspeichern in Default-Word-Vorlage

my\_doc <- read\_docx() %>% body\_add\_flextable(value = ft\_ae)  
print(my\_doc, target = "table\_ae\_lang.docx")

## Abspeichern in benutzerdefinierter Vorlage

my\_doc <- read\_docx("table\_vorlage.docx") %>% body\_add\_flextable(value = ft\_ae)  
print(my\_doc, target = "table\_ae\_quer.docx")