This blog post is just an answer to a colleague to provide R code for the generation of Adverse Event tables. And it is also nice to have the code available when I need it in the future. Probably I will pull my hair at the horrible code, but this gives room to enhance it later.

**Functions**

First I define all functions to be used. I reuse some of the ideas in the post where I show how to make publishable tables using purrr.

ae\_n\_pct <- function(data, var, group, level = 1) {

var <- ensym(var)

group <- ensym(group)

data %>%

group\_by(subjectid, !!group, !!var) %>%

summarise(n = sum(!!var)) %>%

group\_by(!!group, !!var) %>%

summarise(n\_ae = sum(n),

n\_pat = n()) %>%

group\_by(!!group) %>%

mutate(N\_pat = sum(n\_pat),

pct = round(n\_pat/N\_pat\*100,digits = 1),

txt = paste0(n\_pat, " (", pct, "%)")) %>%

filter(!!var %in% !!level) %>%

ungroup %>%

select(!!group, txt) %>%

deframe

}

ae\_N\_n\_pct <- function(data, var, group, level = 1) {

var <- ensym(var)

group <- ensym(group)

data %>%

group\_by(subjectid, !!group) %>%

summarise(n = sum(!!var)) %>%

mutate(!!var := if\_else(n==0, 0, 1)) %>%

group\_by(!!group, !!var) %>%

summarise(n\_ae = sum(n),

n\_pat = n()) %>%

group\_by(!!group) %>%

mutate(N\_pat = sum(n\_pat),

pct = round(n\_pat/N\_pat\*100,digits = 1),

txt = paste0("[", n\_ae,"] ", n\_pat, " (", pct, "%)")) %>%

mutate(txt = if\_else(n\_ae == 0, "[0] 0 (0%)", txt)) %>%

filter(!!var %in% !!level) %>%

ungroup %>%

select(!!group, txt) %>%

deframe

}

stats\_exec <- function(f, data, var, group, ...){

exec(f, data, var, group, !!!(...))

}

Then I do a bit of data wrangling. The mock-up data can be downloaded in .rds format [here](https://icostatistics.no/datasets/adae.rds)

adae <- readRDS("static/datasets/adae.rds") %>%

mutate(anyae = if\_else([is.na](http://is.na)(pt), 0, 1),

sae = if\_else([is.na](http://is.na)(pt), 0, sae)

) %>%

group\_by(subjectid) %>%

mutate(n\_ae = sum(anyae),

one\_ae = n\_ae == 1,

two\_ae = n\_ae == 2,

three\_plus\_ae = n\_ae > 2,

anysae = max(sae)) %>%

ungroup

**Summary of Adverse Events**

The summary of Adverse Events is a nice table just summing up the adverse events in the trial. Note the “[N] n (%)”-format which is the number of events, number of patients with events and percentage of patients with event.

arms <- c("Active", "Control")

total\_n <- n\_distinct(adae$subjectid)

header\_ae <- adae %>%

group\_by(trt, subjectid) %>%

summarise(n=n()) %>%

group\_by(trt) %>%

summarise(n = n()) %>%

ungroup() %>%

mutate(armtxt = arms) %>%

mutate(txt = paste0(armtxt, " (N=", n, ")")) %>%

select(txt) %>%

deframe

ae\_summary\_table <- tribble(

~text, ~var, ~f,

"Number of AEs", "anyae", "ae\_N\_n\_pct",

"Number of patients with any AEs?", "anyae", "ae\_n\_pct",

"Number of patients with one AE", "one\_ae", "ae\_n\_pct",

"Number of patients with two AE", "two\_ae", "ae\_n\_pct",

"Number of patients with three or more AEs", "three\_plus\_ae", "ae\_n\_pct",

"Number of SAEs", "sae", "ae\_N\_n\_pct",

"Number of patients with any SAEs?", "anysae","ae\_n\_pct"

)

ae\_summary\_table %>%

mutate(data = list(adae),

group = "trt",

param = list(level = 1)) %>%

mutate(res = pmap(list(f, data, var, group, param), stats\_exec)) %>%

mutate(id = map(res,names)) %>%

unnest(c(res, id)) %>%

mutate(id = paste0("txt", id)) %>%

pivot\_wider(values\_from = res, names\_from = id) %>%

select(text, starts\_with("txt")) %>%

kable(col.names = c("Parameter", header\_ae),

caption = "Summary of Adverse Events",

booktabs = TRUE)

| Table 1: Summary of Adverse Events | | |
| --- | --- | --- |
| **Parameter** | **Active (N=81)** | **Control (N=80)** |
| Number of AEs | [149] 74 (91.4%) | [165] 79 (98.8%) |
| Number of patients with any AEs? | 74 (86%) | 79 (92.9%) |
| Number of patients with one AE | 14 (17.3%) | 12 (15%) |
| Number of patients with two AE | 13 (16%) | 16 (20%) |
| Number of patients with three or more AEs | 49 (60.5%) | 52 (65%) |
| Number of SAEs | [4] 4 (4.9%) | [2] 2 (2.5%) |
| Number of patients with any SAEs? | 6 (7.4%) | 6 (7.5%) |

**Adverse Events by System Organ Class and Preferred term**

This table is almost a listing, but it gives a nice overview of all Adverse Events in the trial. First we need to make function which does most of the work.

ae\_table\_fns <- function(data, filtervar){

filtervar = ensym(filtervar)

data %>%

group\_by(trt) %>%

mutate(N\_pat = n\_distinct(subjectid)) %>%

filter(!!filtervar == 1) %>%

group\_by(subjectid, trt, N\_pat, soc, pt) %>%

summarise(n\_ae = n()) %>%

filter(![is.na](http://is.na)(pt)) %>%

group\_by(trt, N\_pat, soc, pt) %>%

summarise(n\_pat = n(),

n\_ae = sum(n\_ae)) %>%

mutate(pct = round(n\_pat/N\_pat\*100,digits = 1),

txt = paste0("[", n\_ae,"] ", n\_pat, " (", pct, "%)"),

arm = paste0("arm", trt)) %>%

ungroup %>% select(arm, soc, pt, txt) %>%

pivot\_wider(values\_from = txt, names\_from = arm) %>%

mutate\_at(vars(starts\_with("arm")), ~if\_else([is.na](http://is.na" \t "_blank)(.), "", .)) %>%

arrange(soc, pt) %>% group\_by(soc2 = soc) %>%

mutate(soc = if\_else(row\_number() != 1, "", soc)) %>% ungroup() %>% select(-soc2)

}

adae %>%

bind\_rows(adae, .id="added") %>%

filter(![is.na](http://is.na)(pt)) %>%

mutate(pt = if\_else(added == 2, "#Total", pt)) %>%

mutate(all = 1) %>%

ae\_table\_fns("all") %>%

knitr::kable(col.names = c("System Organ Class", "Preferred Term", header\_ae),

caption = " Adverse Events by System Organ Class and Preferred term\*",

booktabs = TRUE,

longtable = TRUE)

| Table 2: Adverse Events by System Organ Class and Preferred term\* | | | |
| --- | --- | --- | --- |
| **System Organ Class** | **Preferred Term** | **Active (N=81)** | **Control (N=80)** |
| Blood and lymphatic system disorders | #Total | [1] 1 (1.4%) | [2] 2 (2.5%) |
|  | Increased tendency to bruise |  | [1] 1 (1.3%) |
|  | Neutropenia | [1] 1 (1.4%) |  |
|  | Thrombocytopenia |  | [1] 1 (1.3%) |
| Cardiac disorders | #Total | [2] 2 (2.7%) | [2] 2 (2.5%) |
|  | Palpitations | [2] 2 (2.7%) | [2] 2 (2.5%) |
| Eye disorders | #Total | [2] 2 (2.7%) | [5] 5 (6.3%) |
|  | Dry eye |  | [2] 2 (2.5%) |
|  | Eye irritation | [2] 2 (2.7%) | [1] 1 (1.3%) |
|  | Vision blurred |  | [2] 2 (2.5%) |
| Gastrointestinal disorders | #Total | [42] 32 (43.2%) | [25] 19 (24.1%) |
|  | Abdominal discomfort | [2] 2 (2.7%) | [1] 1 (1.3%) |
|  | Abdominal pain | [1] 1 (1.4%) |  |
|  | Abdominal pain upper | [1] 1 (1.4%) | [1] 1 (1.3%) |
|  | Angular cheilitis | [1] 1 (1.4%) |  |
|  | Constipation |  | [1] 1 (1.3%) |
|  | Diarrhoea | [3] 3 (4.1%) |  |
|  | Diverticulum intestinal | [1] 1 (1.4%) |  |
|  | Dyspepsia |  | [1] 1 (1.3%) |
|  | Flatulence |  | [1] 1 (1.3%) |
|  | Gastritis |  | [2] 2 (2.5%) |
|  | Gastrooesophageal reflux disease |  | [2] 2 (2.5%) |
|  | Glossodynia |  | [1] 1 (1.3%) |
|  | Lip ulceration |  | [1] 1 (1.3%) |
|  | Mouth ulceration | [1] 1 (1.4%) | [2] 2 (2.5%) |
|  | Nausea | [25] 22 (29.7%) | [11] 10 (12.7%) |
|  | Oral mucosal blistering | [1] 1 (1.4%) | [1] 1 (1.3%) |
|  | Paraesthesia oral | [1] 1 (1.4%) |  |
|  | Tooth loss | [1] 1 (1.4%) |  |
|  | Vomiting | [4] 4 (5.4%) |  |
| General disorders and administration site conditions | #Total | [12] 12 (16.2%) | [12] 11 (13.9%) |
|  | Asthenia |  | [1] 1 (1.3%) |
|  | Fatigue | [4] 4 (5.4%) | [5] 5 (6.3%) |
|  | Impaired healing | [1] 1 (1.4%) |  |
|  | Influenza like illness |  | [1] 1 (1.3%) |
|  | Infusion site swelling | [1] 1 (1.4%) |  |
|  | Injection site bruising |  | [1] 1 (1.3%) |
|  | Injection site reaction |  | [1] 1 (1.3%) |
|  | Malaise |  | [1] 1 (1.3%) |
|  | Nodule | [1] 1 (1.4%) |  |
|  | Pain | [1] 1 (1.4%) |  |
|  | Pyrexia | [4] 4 (5.4%) | [2] 2 (2.5%) |
| Immune system disorders | #Total | [1] 1 (1.4%) | [2] 2 (2.5%) |
|  | Hypersensitivity | [1] 1 (1.4%) | [2] 2 (2.5%) |
| Infections and infestations | #Total | [19] 18 (24.3%) | [38] 31 (39.2%) |
|  | Borrelia infection |  | [1] 1 (1.3%) |
|  | Bronchitis | [1] 1 (1.4%) | [1] 1 (1.3%) |
|  | Conjunctivitis |  | [1] 1 (1.3%) |
|  | Conjunctivitis bacterial |  | [1] 1 (1.3%) |
|  | Diverticulitis |  | [1] 1 (1.3%) |
|  | Epididymitis |  | [1] 1 (1.3%) |
|  | Furuncle | [1] 1 (1.4%) |  |
|  | Gastroenteritis | [2] 2 (2.7%) |  |
|  | Gastroenteritis viral |  | [1] 1 (1.3%) |
|  | Gingival abscess |  | [1] 1 (1.3%) |
|  | Herpes virus infection |  | [1] 1 (1.3%) |
|  | Infected skin ulcer | [1] 1 (1.4%) |  |
|  | Influenza | [1] 1 (1.4%) | [2] 2 (2.5%) |
|  | Localised infection | [1] 1 (1.4%) | [1] 1 (1.3%) |
|  | Nail bed infection |  | [1] 1 (1.3%) |
|  | Nasopharyngitis | [5] 5 (6.8%) | [11] 10 (12.7%) |
|  | Oral herpes |  | [1] 1 (1.3%) |
|  | Otitis media | [1] 1 (1.4%) |  |
|  | Respiratory tract infection |  | [1] 1 (1.3%) |
|  | Rhinitis |  | [1] 1 (1.3%) |
|  | Sinusitis | [1] 1 (1.4%) |  |
|  | Tinea versicolour |  | [1] 1 (1.3%) |
|  | Upper respiratory tract infection | [4] 4 (5.4%) | [8] 8 (10.1%) |
|  | Urinary tract infection | [1] 1 (1.4%) | [1] 1 (1.3%) |
|  | Urinary tract infection bacterial |  | [1] 1 (1.3%) |
| Injury, poisoning and procedural complications | #Total | [3] 3 (4.1%) | [7] 7 (8.9%) |
|  | Arthropod bite |  | [2] 2 (2.5%) |
|  | Arthropod sting |  | [1] 1 (1.3%) |
|  | Contusion |  | [1] 1 (1.3%) |
|  | Incorrect dose administered | [1] 1 (1.4%) |  |
|  | Joint dislocation | [1] 1 (1.4%) |  |
|  | Limb injury |  | [1] 1 (1.3%) |
|  | Road traffic accident |  | [1] 1 (1.3%) |
|  | Skin wound | [1] 1 (1.4%) | [1] 1 (1.3%) |
| Investigations | #Total | [21] 17 (23%) | [15] 13 (16.5%) |
|  | Alanine aminotransferase increased | [13] 11 (14.9%) | [9] 9 (11.4%) |
|  | Biopsy prostate | [1] 1 (1.4%) |  |
|  | Blood bilirubin increased |  | [2] 2 (2.5%) |
|  | Blood pressure decreased | [1] 1 (1.4%) |  |
|  | Blood pressure increased | [1] 1 (1.4%) |  |
|  | Blood triglycerides increased |  | [1] 1 (1.3%) |
|  | Chest X-ray abnormal |  | [1] 1 (1.3%) |
|  | Hepatic enzyme increased | [3] 3 (4.1%) |  |
|  | Platelet count decreased |  | [2] 2 (2.5%) |
|  | Transaminases increased | [1] 1 (1.4%) |  |
|  | Weight increased | [1] 1 (1.4%) |  |
| Metabolism and nutrition disorders | #Total |  | [3] 3 (3.8%) |
|  | Decreased appetite |  | [1] 1 (1.3%) |
|  | Hyperlipidaemia |  | [1] 1 (1.3%) |
|  | Hypertriglyceridaemia |  | [1] 1 (1.3%) |
| Musculoskeletal and connective tissue disorders | #Total | [7] 7 (9.5%) | [6] 6 (7.6%) |
|  | Arthralgia | [1] 1 (1.4%) |  |
|  | Back pain | [1] 1 (1.4%) |  |
|  | Groin pain |  | [1] 1 (1.3%) |
|  | Intervertebral disc protrusion | [1] 1 (1.4%) |  |
|  | Musculoskeletal pain | [1] 1 (1.4%) | [1] 1 (1.3%) |
|  | Neck pain |  | [2] 2 (2.5%) |
|  | Pain in extremity | [2] 2 (2.7%) | [1] 1 (1.3%) |
|  | Rheumatoid arthritis | [1] 1 (1.4%) |  |
|  | Rotator cuff syndrome |  | [1] 1 (1.3%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | #Total | [1] 1 (1.4%) |  |
|  | Malignant melanoma | [1] 1 (1.4%) |  |
| Nervous system disorders | #Total | [8] 8 (10.8%) | [17] 15 (19%) |
|  | Anosmia | [1] 1 (1.4%) |  |
|  | Dementia | [1] 1 (1.4%) |  |
|  | Dizziness | [2] 2 (2.7%) | [6] 5 (6.3%) |
|  | Dysgeusia | [1] 1 (1.4%) | [1] 1 (1.3%) |
|  | Headache | [2] 2 (2.7%) | [4] 4 (5.1%) |
|  | Hypoaesthesia |  | [2] 2 (2.5%) |
|  | Muscle contractions involuntary | [1] 1 (1.4%) |  |
|  | Paraesthesia |  | [2] 2 (2.5%) |
|  | Taste disorder |  | [1] 1 (1.3%) |
|  | Tension headache |  | [1] 1 (1.3%) |
| Psychiatric disorders | #Total | [2] 2 (2.7%) | [2] 2 (2.5%) |
|  | Anxiety | [1] 1 (1.4%) |  |
|  | Insomnia |  | [2] 2 (2.5%) |
|  | Terminal insomnia | [1] 1 (1.4%) |  |
| Renal and urinary disorders | #Total | [1] 1 (1.4%) | [1] 1 (1.3%) |
|  | Dysuria |  | [1] 1 (1.3%) |
|  | Renal mass | [1] 1 (1.4%) |  |
| Reproductive system and breast disorders | #Total | [1] 1 (1.4%) | [1] 1 (1.3%) |
|  | Hypomenorrhoea | [1] 1 (1.4%) |  |
|  | Uterine polyp |  | [1] 1 (1.3%) |
| Respiratory, thoracic and mediastinal disorders | #Total | [8] 8 (10.8%) | [7] 7 (8.9%) |
|  | Cough | [3] 3 (4.1%) | [2] 2 (2.5%) |
|  | Dysphonia |  | [1] 1 (1.3%) |
|  | Dyspnoea | [1] 1 (1.4%) | [1] 1 (1.3%) |
|  | Epistaxis | [2] 2 (2.7%) |  |
|  | Interstitial lung disease |  | [1] 1 (1.3%) |
|  | Nasal discomfort |  | [1] 1 (1.3%) |
|  | Oropharyngeal pain | [2] 2 (2.7%) |  |
|  | Throat tightness |  | [1] 1 (1.3%) |
| Skin and subcutaneous tissue disorders | #Total | [14] 12 (16.2%) | [17] 17 (21.5%) |
|  | Acne | [1] 1 (1.4%) |  |
|  | Alopecia | [4] 4 (5.4%) | [2] 2 (2.5%) |
|  | Blister | [4] 3 (4.1%) | [1] 1 (1.3%) |
|  | Erythema | [1] 1 (1.4%) |  |
|  | Hyperhidrosis | [1] 1 (1.4%) |  |
|  | Night sweats |  | [1] 1 (1.3%) |
|  | Pain of skin |  | [1] 1 (1.3%) |
|  | Pruritus |  | [2] 2 (2.5%) |
|  | Purpura |  | [1] 1 (1.3%) |
|  | Rash | [2] 2 (2.7%) | [6] 6 (7.6%) |
|  | Rash erythematous |  | [1] 1 (1.3%) |
|  | Urticaria | [1] 1 (1.4%) | [2] 2 (2.5%) |
| Social circumstances | #Total |  | [1] 1 (1.3%) |
|  | Stress at work |  | [1] 1 (1.3%) |
| Surgical and medical procedures | #Total | [2] 2 (2.7%) | [1] 1 (1.3%) |
|  | Parathyroidectomy | [1] 1 (1.4%) |  |
|  | Rehabilitation therapy | [1] 1 (1.4%) |  |
|  | Rheumatoid nodule removal |  | [1] 1 (1.3%) |
| Vascular disorders | #Total | [2] 2 (2.7%) | [1] 1 (1.3%) |
|  | Hypertension | [2] 2 (2.7%) | [1] 1 (1.3%) |

**Serious Adverse Events by System Organ Class and Preferred term**

Then the sub-table with only the serious adverse events.

adae %>%

bind\_rows(adae, .id="added") %>%

filter(![is.na](http://is.na)(pt)) %>%

mutate(pt = if\_else(added == 2, "#Total", pt)) %>%

ae\_table\_fns("sae") %>%

knitr::kable( col.names = c("System Organ Class", "Preferred Term", header\_ae),

caption = "Serious Adverse Events by System Organ Class and Preferred term\*",

booktabs = TRUE,

longtable = TRUE)

| Table 3: Serious Adverse Events by System Organ Class and Preferred term\* | | | |
| --- | --- | --- | --- |
| **System Organ Class** | **Preferred Term** | **Active (N=81)** | **Control (N=80)** |
| General disorders and administration site conditions | #Total | [1] 1 (1.4%) |  |
|  | Pyrexia | [1] 1 (1.4%) |  |
| Infections and infestations | #Total |  | [1] 1 (1.3%) |
|  | Epididymitis |  | [1] 1 (1.3%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | #Total | [1] 1 (1.4%) |  |
|  | Malignant melanoma | [1] 1 (1.4%) |  |
| Reproductive system and breast disorders | #Total |  | [1] 1 (1.3%) |
|  | Uterine polyp |  | [1] 1 (1.3%) |
| Surgical and medical procedures | #Total | [2] 2 (2.7%) |  |
|  | Parathyroidectomy | [1] 1 (1.4%) |  |
|  | Rehabilitation therapy | [1] 1 (1.4%) |  |

Usually there is also a table of probable/possible study treatment related AE/SAEs, and maybe also a AE/SAE of special interest table. They are made similarly to the SAE table.

**Most common Adverse events**

Lastly a table of the most common Adverse events. It is easy to change the treshold.

adae %>%

filter(![is.na](http://is.na)(pt)) %>%

group\_by(trt) %>%

mutate(N\_pat = n\_distinct(subjectid)) %>%

group\_by(subjectid, trt, N\_pat, soc, pt) %>%

summarise(n\_ae = n()) %>%

filter(![is.na](http://is.na)(pt)) %>%

group\_by(trt, N\_pat, soc, pt) %>%

summarise(n\_pat = n(),

n\_ae = sum(n\_ae)) %>%

mutate(pct = round(n\_pat/N\_pat\*100,digits = 1),

txt = paste0("[", n\_ae,"] ", n\_pat, " (", pct, "%)"),

arm = paste0("arm", trt)) %>%

group\_by(pt) %>%

mutate(N\_pat = sum(n\_pat),

pct\_tot = N\_pat /total\_n) %>%

filter(pct\_tot>0.05) %>%

ungroup %>%

select(arm, soc, pt, txt, pct\_tot) %>%

pivot\_wider(values\_from = txt, names\_from = arm) %>%

mutate\_at(vars(starts\_with("arm")), ~if\_else([is.na](http://is.na" \t "_blank)(.), "", .)) %>%

arrange(desc(pct\_tot)) %>% select( pt, everything()) %>% select(-pct\_tot, -soc) %>%

knitr::kable( col.names = c( "Preferred Term", header\_ae),

caption = "Most common Adverse Events (more than 5 percent) by Preferred Term",

booktabs = TRUE,

longtable = TRUE)

| Table 4: Most common Adverse Events (more than 5 percent) by Preferred Term | | |
| --- | --- | --- |
| **Preferred Term** | **Active (N=81)** | **Control (N=80)** |
| Nausea | [25] 22 (29.7%) | [11] 10 (12.7%) |
| Alanine aminotransferase increased | [13] 11 (14.9%) | [9] 9 (11.4%) |
| Nasopharyngitis | [5] 5 (6.8%) | [11] 10 (12.7%) |
| Upper respiratory tract infection | [4] 4 (5.4%) | [8] 8 (10.1%) |
| Fatigue | [4] 4 (5.4%) | [5] 5 (6.3%) |
| Rash | [2] 2 (2.7%) | [6] 6 (7.6%) |
| Dizziness | [2] 2 (2.7%) | [6] 5 (6.3%) |
| Pyrexia | [4] 4 (5.4%) | [2] 2 (2.5%) |
| Headache | [2] 2 (2.7%) | [4] 4 (5.1%) |
| Alopecia | [4] 4 (5.4%) | [2] 2 (2.5%) |