```
-- Attaching core tidyverse packages ----- tidyverse 2.0.0 --
v dplyr 1.1.4
                     v readr
                                   2.1.5
v forcats 1.0.0 v stringr 1.5.1
v ggplot2 3.5.1 v tibble 3.2.1
v lubridate 1.9.3 v tidyr 1.3.1
            1.0.2
v purrr
-- Conflicts ----- tidyverse_conflicts() --
x purrr::%||%() masks base::%||%()
x dplyr::filter() masks stats::filter()
x dplyr::lag() masks stats::lag()
i Use the conflicted package (<a href="http://conflicted.r-lib.org/">http://conflicted.r-lib.org/</a>) to force all conflicts to become
library(knitr)
library(MASS)
Attaching package: 'MASS'
The following object is masked from 'package:dplyr':
    select
library(patchwork)
Attaching package: 'patchwork'
The following object is masked from 'package:MASS':
    area
library(broom)
library(rpact)
Attaching package: 'rpact'
```

library(tidyverse)

```
The following object is masked from 'package:knitr':
    kable
The following object is masked from 'package:dplyr':
    pull
library(effsize)
library(pwr)
::: {.cell}
```{.r .cell-code}
data <- read.csv("data/cookiecats.csv") # import dataset or subset
data$retention_1 <- as.logical(data$retention_1)</pre>
data$retention_7 <- as.logical(data$retention_7)</pre>
data$retention_1 <- as.numeric(data$retention_1)</pre>
data$retention_7 <- as.numeric(data$retention_7)</pre>
calculate the sum users and users per group
nall <- nrow(data)</pre>
groupnumber <- table(data$version)</pre>
groupnumber
gate_30 gate_40
 44700 45489
the average game rounds per group and whole
agrall <- mean(data$sum_gamerounds)</pre>
agr <- tapply(data$sum_gamerounds, data$version, mean)</pre>
the retention rate per group and whole
day1
ret.1 <- mean(data$retention_1)</pre>
ret34.1 <- tapply(data$retention_1,data$version, mean)</pre>
Count.1 <- table(data$retention_1, data$version)</pre>
day7
ret.7 <- mean(data$retention_7)</pre>
ret34.7 <- tapply(data$retention_7,data$version, mean)</pre>
Count.7 <- table(data$retention_7, data$version)</pre>
SRM checking
```

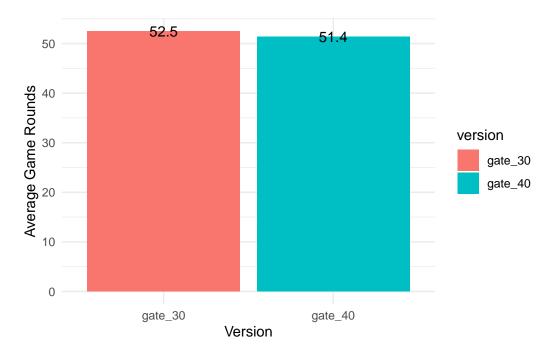
```
n30 <- 44700
n40 <- 45489
total_number <- n40 + n30
observed <- c(n30, n40)
expected <- c(total_number/2, total_number/2)
srm_test <- chisq.test(observed, p = expected / sum(expected))
print(srm_test)</pre>
```

```
Chi-squared test for given probabilities data: observed
```

X-squared = 6.9024, df = 1, p-value = 0.008608

:::

```
data <- read.csv("data/cookiecats_subset.csv")
data$retention_1 <- as.logical(data$retention_1)
data$retention_7 <- as.logical(data$retention_7)
data$retention_1 <- as.numeric(data$retention_1)
data$retention_7 <- as.numeric(data$retention_7)
ret.1 <- mean(data$retention_1)
total_number <- n40 + n30
ret.7 <- mean(data$retention_7)
agrall <- mean(data$sum_gamerounds)</pre>
```



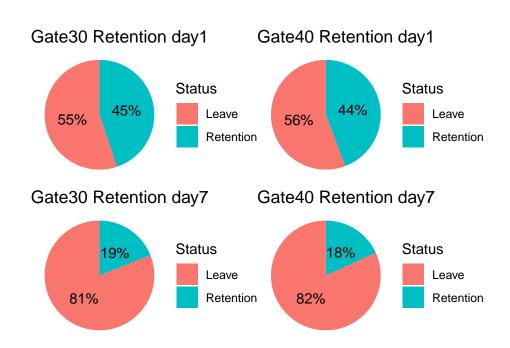
```
nall <- nrow(data)</pre>
n30 <- 44000
n40 <- 44000
gate_30_data <- data[data$version == "gate_30",] # version gate_30</pre>
gate_40_data <- data[data$version == "gate_40",] # version gate_40</pre>
avgr30 <- mean(gate_30_data$sum_gamerounds)</pre>
avgr40 <- mean(gate_40_data$sum_gamerounds)</pre>
reten_1_30 <- mean(gate_30_data$retention_1)</pre>
reten_1_40 <- mean(gate_40_data$retention_1)</pre>
reten_1_all <- mean(data$retention_1)</pre>
reten_7_30 <- mean(gate_30_data$retention_7)</pre>
reten_7_40 <- mean(gate_40_data$retention_7)</pre>
reten_7_all <- mean(data$retention_7)</pre>
leave_1_30 <- 1 - reten_1_30
leave_1_40 <- 1 - reten_1_40
leave_1_all <- 1 - reten_1_all</pre>
leave_7_30 <- 1 - reten_7_30
leave_7_40 <- 1 - reten_7_40
leave_7_all <- 1 - reten_7_all</pre>
pie <- function(reten_value, leave_value, title) {</pre>
 df <- data.frame(</pre>
 category = c("Retention", "Leave"),
```

```
value = c(reten_value, leave_value)
)

ggplot(df, aes(x = "", y = value, fill = category)) +
 geom_bar(width = 1, stat = "identity") +
 coord_polar("y", start = 0) +
 geom_text(aes(label = scales::percent(value/sum(value))),
 position = position_stack(vjust = 0.5))+
 labs(title = title, fill = "Status") +
 theme_void()
}

p1 <- pie(reten_1_30, leave_1_30, "Gate30 Retention day1")
p2 <- pie(reten_1_40, leave_1_40, "Gate40 Retention day7")
p3 <- pie(reten_7_30, leave_7_30, "Gate30 Retention day7")
p4 <- pie(reten_7_40, leave_7_40, "Gate40 Retention day7")

(p1 | p2) / (p3 | p4)</pre>
```



```
library(pwr)
library(effsize)
using equation 5.11
var30 <- var(gate_30_data$sum_gamerounds)</pre>
```

```
var40 <- var(gate_40_data$sum_gamerounds)</pre>
se30gr <-sd(gate_30_data$sum_gamerounds)</pre>
se40gr <- sd(gate_40_data$sum_gamerounds)</pre>
std_pooled_gr \leftarrow sqrt(((n30 - 1)*var30) + ((n40 - 1)*var40))
 /(n30 + n40 - 2))
d.gr <- abs(avgr30 - avgr40)
r \leftarrow 1
n_{gr} < ((1 + r)*((q_{norm}(0.975) + q_{norm}(0.8))^2) * (std_pooled_gr^2))/
 (1 * (d.gr^2))
#using package by cohend's d
cohend <- cohen.d(gate_30_data$sum_gamerounds,gate_40_data$sum_gamerounds,</pre>
 pooled = TRUE)
 cohen.d <- cohend$estimate</pre>
n gr1 <- pwr.t.test(d = cohen.d, sig.level = 0.05, power = 0.8,
 type = "two.sample",
 alternative = "two.sided")
n.gr <- n_gr1$n
power_value <- pwr.t.test(d = cohen.d, n = 44000, sig.level = 0.05,
 type = "two.sample", alternative = "two.sided")
using equation 5.12
For day1 retention rate
std_pooled_1 <- sqrt((reten_1_30*(1 - reten_1_30)) +
 (reten_1_40*(1 - reten_1_40)*r))
std_pooled_1^2 is the variance day1
d.ren1 <- abs(reten_1_30 - reten_1_40)
N_{ren1} \leftarrow ((q_{norm}(0.975) + (q_{norm}(0.8)))^2 * (std_{pooled_1^2}))/
 (d.ren1²)
std_pooled_7^2 is the variance day7
std_pooled_7 \leftarrow sqrt((reten_7_30*(1 - reten_7_30)) +
 (reten_7_40*(1 - reten_7_40)*r))
d.ren7 <- abs(reten_7_30 - reten_7_40)
N_{ren7} < ((q_{norm}(0.975) + (q_{norm}(0.8)))^2 * (std_{pooled_7^2}))/
 (d.ren7^2)
using cohen'h
cohen.h1 <- ES.h(reten_1_30,reten_1_40)</pre>
N.reten1 <- pwr.2p.test(h = cohen.h1, sig.level = 0.05, power = 0.8,
 alternative = "two.sided")
N.ren1 <- N.reten1$n
cohen.h7 <- ES.h(reten_7_30,reten_7_40)</pre>
N.reten7 <- pwr.2p.test(h = cohen.h7, sig.level = 0.05, power = 0.8,
```

#### [1] 0.0912466

```
se.7 <- sqrt(reten_7_all*(1 - reten_7_all)*(1/n30+1/n40))
z.value <- (reten_7_30 - reten_7_40)/se.7
p.value <- 2*(1 - pnorm(abs(z.value)))
print(p.value)</pre>
```

#### [1] 0.004891535

```
buile chi-squre statistic
n30true1 <- sum(gate_30_data$retention_1 ==1)
n40true1 <- sum(gate_40_data$retention_1 ==1)
n30true7 <- sum(gate_30_data$retention_7 ==1)
n40true7 <- sum(gate_40_data$retention_7 ==1)
stay1 <- c(n30true1,n40true1)
stay7 <- c(n30true7,n40true7)
n <- c(n30,n40)
ztest <- prop.test(stay7,n,alternative = "two.sided")# change stay1 or stay7
print(ztest)</pre>
```

2-sample test for equality of proportions with continuity correction

data: stay7 out of n

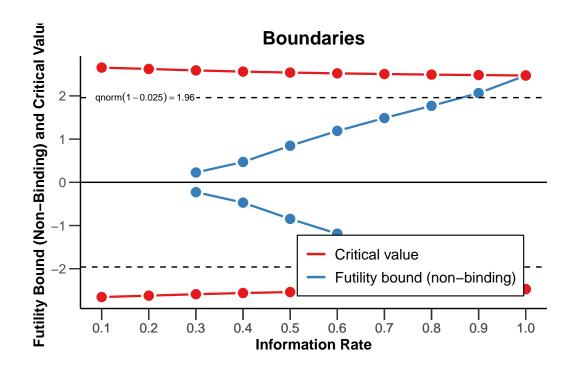
```
X-squared = 7.8705, df = 1, p-value = 0.005025
alternative hypothesis: two.sided
95 percent confidence interval:
 0.002219398 0.012553329
sample estimates:
 prop 1
 prop 2
0.1899545 0.1825682
established logistical model
data$version <- factor(data$version, levels = c("gate_40", "gate_30"))</pre>
logmodel <- glm(retention_7 ~ version, family = binomial(link = "logit"),</pre>
 data = data) # retention_7 or retention_1
summary(logmodel)
Call:
glm(formula = retention_7 ~ version, family = binomial(link = "logit"),
 data = data)
Coefficients:
 Estimate Std. Error z value Pr(>|z|)
(Intercept) -1.49904 0.01234 -121.473 < 2e-16 ***
versiongate_30 0.04874
 0.01732
 2.814 0.00489 **
Signif. codes: 0 '***' 0.001 '**' 0.05 '.' 0.1 ' ' 1
(Dispersion parameter for binomial family taken to be 1)
 Null deviance: 84613 on 87999 degrees of freedom
Residual deviance: 84605 on 87998 degrees of freedom
AIC: 84609
Number of Fisher Scoring iterations: 4
RAhat <- predict(logmodel, type = "response")</pre>
mean(RAhat)
```

[1] 0.1862614

```
odds \leftarrow \exp(-1.49904 + 0.04874 * 1)
```

```
loading new data with time variable
data1 <- read.csv("data/cookiecats_subset1.csv")
data1$retention_1_t <- as.logical(data1$retention_1_t)
data1$retention_7_t <- as.logical(data1$retention_7_t)
data1$retention_1_t <- as.numeric(data1$retention_1_t)
data1$retention_7_t <- as.numeric(data1$retention_7_t)
data1$retention_1_c <- as.logical(data1$retention_1_c)
data1$retention_7_c <- as.logical(data1$retention_7_c)
data1$retention_1_c <- as.numeric(data1$retention_1_c)
data1$retention_1_c <- as.numeric(data1$retention_1_c)
data1$retention_7_c <- as.numeric(data1$retention_7_c)</pre>
```

```
choosing pocock boundary
library(rpact)
Example: beta-spending function approach with Pocock spending function
function and Pocock beta-spending function
designgr <- getDesignGroupSequential(
 sided = 2, alpha = 0.05, beta = 0.2, kMax = 10,
 informationRates = c(0.1, 0.2, 0.3,0.4,0.5,0.6,0.7,0.8,0.9,1),
 typeOfDesign = "asP",
 typeBetaSpending = "bsP",bindingFutility = FALSE,twoSidedPower = FALSE
)
plot(designgr, type = 1)</pre>
```



#### summary(designgr)

Sequential analysis with a maximum of 10 looks (group sequential design)

Pocock type alpha spending design and Pocock type beta spending, non-binding futility, two-sided overall significance level 5%, power 80%, undefined endpoint, inflation factor 1.4339, ASN H1 0.7287, ASN H0 0.7985, ASN H0 0.7059.

Stage	1	2	3	4	5	6	7	8	9	10
Planned infor-	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
ma- tion rate										
Efficacy 2 bound-	2.655	2.623	2.590	2.562	2.540	2.521	2.506	2.493	2.482	2.472
ary (z- value										
scale)										

Stage	1	2	3	4	5	6	7	8	9	10
Stage levels (one-	0.0040	0.0044	0.0048	0.0052	0.0055	0.0058	0.0061	0.0063	0.0065	0.0067
sided) Futility bound-			0.227	0.471	0.846	1.189	1.488	1.770	2.065	
ary (z- value scale)										
Cumula alpha spent	at <b>0</b> z <b>0</b> 079	0.0148	0.0208	0.0262	0.0310	0.0354	0.0395	0.0432	0.0467	0.0500
Cumula beta spent	at <b>0</b> ve	0	0.0342	0.0646	0.0922	0.1173	0.1403	0.1616	0.1815	0.2000
Cumula	at <b>0</b> v <b>0</b> 554	0.1499	0.2640	0.3821	0.4937	0.5922	0.6737	0.7362	0.7785	0.8000
power Futility prob- abili- ties under H1	0	0	0.034	0.030	0.028	0.025	0.023	0.021	0.020	

Sample size calculation for a continuous endpoint

Sequential analysis with a maximum of 10 looks (group sequential design), overall significance level 5% (two-sided). The results were calculated for a two-sample t-test, H0: mu(1) - mu(2) = 0, H1: effect = 1.098, standard deviation = 196.877, power 80%.

Stage	1	2	3	4	5	6	7	8	9	10
Planned infor-	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
ma-										
tion										
rate	0.055	0.000	0.500	0.500	0.540	0.501	0.500	0.409	0.400	0.470
Efficacy bound-	2.655	2.623	2.590	2.562	2.540	2.521	2.506	2.493	2.482	2.472
ary										
(z- value										
scale) Futility			0.227	0.471	0.846	1.189	1.488	1.770	2.065	
bound-			0.221	0.471	0.040	1.109	1.400	1.770	2.000	
ary										
(z-										
value										
scale)										
Cumulat	t0v9554	0.1499	0.2640	0.3821	0.4937	0.5922	0.6737	0.7362	0.7785	0.8000
power	00,0001	0.1400	0.2040	0.0021	0.4501	0.0022	0.0101	0.1002	0.1100	0.0000
-	144687	6289375	2434062	9578750	5723438	1868125	7101281:	3.157501	L <b>0</b> 302188	8. <b>6</b> 446876
of	1110011		_ 10 10 0	00,0,00	0.20100.	10001201	.101201	J. 410.00		,. <b>.</b> 1100,0
sub-										
jects										
Expecte	d735308.	.4								
num-										
ber of										
sub-										
jects										
under										
H1										
Cumulat	t <b>0</b> v <b>0</b> 079	0.0148	0.0208	0.0262	0.0310	0.0354	0.0395	0.0432	0.0467	0.0500
alpha										
spent										
Cumulat	t <b>0</b> ve	0	0.0342	0.0646	0.0922	0.1173	0.1403	0.1616	0.1815	0.2000
beta										
spent										

Stage	1	2	3	4	5	6	7	8	9	10
Two-sided local significance	0.0079	0.0087	0.0096	0.0104	0.0111	0.0117	0.0122	0.0127	0.0131	0.0134
level Lower futil- ity bound- ary			-0.136	-0.244	-0.392	-0.502	-0.582	-0.648	-0.712	
(t) Upper futil- ity bound- ary			0.136	0.244	0.392	0.502	0.582	0.648	0.712	
(t) Overall exit prob- abil- ity (un- der H0)	0.0079	0.0068	0.1855	0.2514	0.2360	0.1487	0.0843	0.0463	0.0236	
Overall exit probability (under H1)	0.0554	0.0945	0.1482	0.1486	0.1391	0.1235	0.1046	0.0838	0.0621	

Stage	1	2	3	4	5	6	7	8	9	10
Exit probability for efficacy (under H0)	0.0079	0.0068	0.0060	0.0054	0.0048	0.0043	0.0038	0.0033	0.0025	
Exit probability for efficacy (under H1)	0.0554	0.0945	0.1141	0.1181	0.1116	0.0985	0.0815	0.0625	0.0423	
Exit probability for futility (under H0)	0	0	0.1795	0.2460	0.2312	0.1443	0.0805	0.0430	0.0211	
Exit probabilative for futilative (under H1)	0	0	0.0341	0.0305	0.0275	0.0251	0.0230	0.0213	0.0198	

## Legend:

• (t): treatment effect scale

# designChargr <- getDesignCharacteristics(designgr) summary(designChargr)</pre>

Sequential analysis with a maximum of 10 looks (group sequential design)

Pocock type alpha spending design and Pocock type beta spending, non-binding futility, two-sided overall significance level 5%, power 80%, undefined endpoint, inflation factor 1.4339, ASN H1 0.7287, ASN H01 0.7985, ASN H0 0.7059.

Stage	1	2	3	4	5	6	7	8	9	10
Planned information	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
rate Efficacy bound- ary (z- value	2.655	2.623	2.590	2.562	2.540	2.521	2.506	2.493	2.482	2.472
scale) Stage levels (one-	0.0040	0.0044	0.0048	0.0052	0.0055	0.0058	0.0061	0.0063	0.0065	0.0067
sided) Futility bound- ary (z- value			0.227	0.471	0.846	1.189	1.488	1.770	2.065	
scale) Cumulat alpha	t <b>0</b> x <b>0</b> 079	0.0148	0.0208	0.0262	0.0310	0.0354	0.0395	0.0432	0.0467	0.0500
spent Cumulat beta	t <b>û</b> ve	0	0.0342	0.0646	0.0922	0.1173	0.1403	0.1616	0.1815	0.2000
spent Cumulat power	t <b>0</b> x <b>0</b> 554	0.1499	0.2640	0.3821	0.4937	0.5922	0.6737	0.7362	0.7785	0.8000

Stage	1	2	3	4	5	6	7	8	9	10
Futility prob- abili- ties under H1	0	0	0.034	0.030	0.028	0.025	0.023	0.021	0.020	

## sampleSizeResultgr[["earlyStop"]]

#### [1] 0.959857

## sampleSizeResultgr[["numberOfSubjects"]]

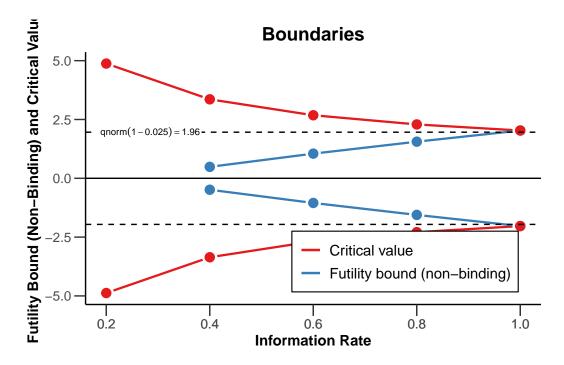
```
[,1]
[1,] 144687.6
[2,] 289375.2
[3,] 434062.9
[4,] 578750.5
[5,] 723438.1
[6,] 868125.7
[7,] 1012813.3
[8,] 1157501.0
[9,] 1302188.6
[10,] 1446876.2
```

## sampleSizeResultgr[["maxNumberOfSubjects"]]

#### [1] 1446876

```
ASNgr <- sampleSizeResultgr[["expectedNumberOfSubjectsH01"]]
fixed_ngr <- 2*n_gr
saverate.gr <- abs((ASNgr - fixed_ngr))/fixed_ngr
(1009039-712317)/1009039
```

## [1] 0.294064



```
summary(design1)
```

Sequential analysis with a maximum of 5 looks (group sequential design)

O'Brien & Fleming type alpha spending design and Pocock type beta spending, non-binding futility, two-sided overall significance level 5%, power 80%, undefined endpoint, inflation factor 1.2066, ASN H1 0.8486, ASN H01 0.8209, ASN H0 0.7126.

Stage	1	2	3	4	5
Planned information rate	20%	40%	60%	80%	100%
Efficacy boundary (z-value scale)	4.877	3.357	2.680	2.290	2.031
Stage levels (one-sided)	< 0.0001	0.0004	0.0037	0.0110	0.0211
Futility boundary (z-value scale)		0.486	1.048	1.556	
Cumulative alpha spent	< 0.0001	0.0008	0.0076	0.0244	0.0500
Cumulative beta spent	0	0.0646	0.1173	0.1616	0.2000
Cumulative power	0.0002	0.0792	0.3855	0.6749	0.8000
Futility probabilities under H1	0	0.065	0.053	0.044	

Sample size calculation for a binary endpoint

Sequential analysis with a maximum of 5 looks (group sequential design), overall significance level 5% (two-sided). The results were calculated for a two-sample test for rates (normal approximation), H0: pi(1) - pi(2) = 0, H1: treatment rate pi(1) = 0.448, control rate pi(2) = 0.443, power 80%.

Stage	1	2	3	4	5
Planned information rate	20%	40%	60%	80%	100%
Efficacy boundary (z-value	4.877	3.357	2.680	2.290	2.031
scale) Futility boundary (z-value scale)		0.486	1.048	1.556	
Cumulative power	0.0002	0.0792	0.3855	0.6749	0.8000
Number of subjects	58435.3	116870.6	175306.0	233741.3	292176.6
Expected number of subjects under H1	205498.2				
Cumulative alpha spent	< 0.0001	0.0008	0.0076	0.0244	0.0500
Cumulative beta spent	0	0.0646	0.1173	0.1616	0.2000
Two-sided local significance level	< 0.0001	0.0008	0.0074	0.0220	0.0423
Lower futility boundary (t)		-0.001	-0.002	-0.003	
Upper futility boundary (t)		0.001	0.002	0.003	
Overall exit probability (under H0)	< 0.0001	0.3740	0.3730	0.1789	
Overall exit probability (under H1)	0.0002	0.1436	0.3589	0.3338	

Stage	1	2	3	4	5
Exit probability for efficacy (under H0)	< 0.0001	0.0008	0.0068	0.0160	
Exit probability for efficacy (under H1)	0.0002	0.0789	0.3063	0.2894	
Exit probability for futility (under H0)	0	0.3732	0.3661	0.1629	
Exit probability for futility (under H1)	0	0.0646	0.0526	0.0444	

## Legend:

• (t): treatment effect scale

designCharr1 <- getDesignCharacteristics(design1)
summary(designCharr1)</pre>

Sequential analysis with a maximum of 5 looks (group sequential design)

O'Brien & Fleming type alpha spending design and Pocock type beta spending, non-binding futility, two-sided overall significance level 5%, power 80%, undefined endpoint, inflation factor 1.2066, ASN H1 0.8486, ASN H01 0.8209, ASN H0 0.7126.

Stage	1	2	3	4	5
Planned information rate	20%	40%	60%	80%	100%
Efficacy boundary (z-value	4.877	3.357	2.680	2.290	2.031
scale) Stage levels (one-sided)	< 0.0001	0.0004	0.0037	0.0110	0.0211

Stage	1	2	3	4	5
Futility		0.486	1.048	1.556	
boundary					
(z-value					
scale)					
Cumulative	< 0.0001	0.0008	0.0076	0.0244	0.0500
alpha spent					
Cumulative	0	0.0646	0.1173	0.1616	0.2000
beta spent					
Cumulative	0.0002	0.0792	0.3855	0.6749	0.8000
power					
Futility	0	0.065	0.053	0.044	
probabilities					
under H1					

## sampleSizeResultGS1[["numberOfSubjects"]]

[,1]

[1,] 58435.32

[2,] 116870.65

[3,] 175305.97

[4,] 233741.29

[5,] 292176.62

## sampleSizeResultGS1[["earlyStop"]]

## [1] 0.8365378

## sampleSizeResultGS1[["maxNumberOfSubjects"]]

#### [1] 292176.6

## sampleSizeResultGS1[["expectedNumberOfSubjectsH1"]]

## [1] 205498.2

```
sampleSizeResultGS1[["expectedNumberOfSubjectsH01"]]
```

[1] 198792.3

```
sampleSizeResultGS1[["expectedNumberOfSubjectsHO"]]
```

[1] 172571.6

```
ASNgr <- sampleSizeResultGS1[["expectedNumberOfSubjectsH01"]]
#stage 1 for retention rate diff testing on day1
data_stage1d1 <- data1[1:29218,]
meand1stage1 <-apply(data_stage1d1[,c("retention_1_t","retention_1_c")],2,mean)
rate1.t <- meand1stage1[1]
rate1.c <- meand1stage1[2]
staystage1_t <- sum(data_stage1d1$retention_1_t)
staystage1_c <- sum(data_stage1d1$retention_1_c)
sizestage1 <- nrow(data_stage1d1)
d1ra.stage1 <- (staystage1_c+staystage1_t)/(2*sizestage1)
se.11 <- sqrt(d1ra.stage1*(1 - d1ra.stage1)*(1/sizestage1+1/sizestage1))
z.value.11 <- (rate1.t - rate1.c)/se.11
unname(z.value.11)
```

[1] 1.290337

```
#p.value.11 <- 2*(1 - pnorm(abs(z.value.11)))
#print(p.value.11)
#saving rates and inflation rate
(242153-172572)/242153</pre>
```

[1] 0.2873431

```
(292177-242153)/242153
```

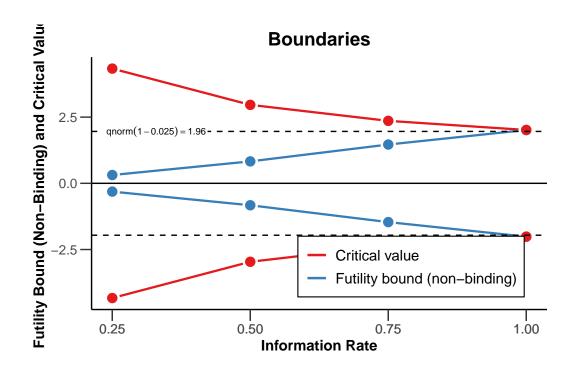
[1] 0.2065801

Sequential analysis with a maximum of 4 looks (group sequential design)

O'Brien & Fleming type alpha spending design and Pocock type beta spending, non-binding futility, two-sided overall significance level 5%, power 80%, undefined endpoint, inflation factor 1.3012, ASN H1 0.8963, ASN H01 0.8438, ASN H0 0.7126.

Stage	1	2	3	4
Planned	25%	50%	75%	100%
information rate				
Efficacy	4.333	2.963	2.359	2.014
boundary				
(z-value scale)				
Stage levels	< 0.0001	0.0015	0.0092	0.0220
(one-sided)				
Futility	0.313	0.828	1.465	
boundary				
(z-value scale)				
Cumulative	< 0.0001	0.0031	0.0193	0.0500
alpha spent				
Cumulative beta	0.0715	0.1240	0.1656	0.2000
spent				
Cumulative	0.0031	0.2405	0.6398	0.8000
power				
Futility	0.071	0.053	0.042	
probabilities				
under H1				

```
plot(design7, type =1)
```



Sample size calculation for a binary endpoint

Sequential analysis with a maximum of 4 looks (group sequential design), overall significance level 5% (two-sided). The results were calculated for a two-sample test for rates (normal approximation), H0: pi(1) - pi(2) = 0, H1: treatment rate pi(1) = 0.19, control rate pi(2) = 0.183, power 80%.

Stage	1	2	3	4
Planned	25%	50%	75%	100%
information ra	te			
Efficacy	4.333	2.963	2.359	2.014
boundary				
(z-value scale)				

Stage	1	2	3	4
Futility	0.313	0.828	1.465	
boundary				
(z-value scale)				
Cumulative	0.0031	0.2405	0.6398	0.8000
power	00051 5	F. 0. T. 10 1	051151	1104000
Number of	28371.7	56743.4	85115.1	113486.8
subjects Expected	78176.8			
number of	10110.0			
subjects under				
H1				
Cumulative	< 0.0001	0.0031	0.0193	0.0500
alpha spent	(0.0001	0.0001	0.0100	0.0000
Cumulative beta	0.0715	0.1240	0.1656	0.2000
spent				
Two-sided local	< 0.0001	0.0030	0.0183	0.0440
significance level				
Lower futility	-0.001	-0.003	-0.004	
boundary (t)				
Upper futility	0.001	0.003	0.004	
boundary (t)				
Overall exit	0.2460	0.4109	0.2499	
probability				
(under H0)	0.0746	0.0000	0.4400	
Overall exit	0.0746	0.2900	0.4408	
probability (under H1)				
Exit probability	< 0.0001	0.0030	0.0151	
for efficacy	₹0.0001	0.0030	0.0101	
(under H0)				
Exit probability	0.0031	0.2374	0.3992	
for efficacy				
(under H1)				
Exit probability	0.2459	0.4079	0.2348	
for futility				
(under H0)				
Exit probability	0.0715	0.0525	0.0416	
for futility				
(under H1)				

## Legend:

• (t): treatment effect scale

## designCharr1 <- getDesignCharacteristics(design1) summary(designCharr1)</pre>

Sequential analysis with a maximum of 5 looks (group sequential design)

O'Brien & Fleming type alpha spending design and Pocock type beta spending, non-binding futility, two-sided overall significance level 5%, power 80%, undefined endpoint, inflation factor 1.2066, ASN H1 0.8486, ASN H01 0.8209, ASN H0 0.7126.

Stage	1	2	3	4	5
Planned information rate	20%	40%	60%	80%	100%
Efficacy boundary (z-value scale)	4.877	3.357	2.680	2.290	2.031
Stage levels (one-sided)	< 0.0001	0.0004	0.0037	0.0110	0.0211
Futility boundary (z-value scale)		0.486	1.048	1.556	
Cumulative alpha spent	< 0.0001	0.0008	0.0076	0.0244	0.0500
Cumulative beta spent	0	0.0646	0.1173	0.1616	0.2000
Cumulative power	0.0002	0.0792	0.3855	0.6749	0.8000
Futility probabilities under H1	0	0.065	0.053	0.044	

## sampleSizeResultGS7[["numberOfSubjects"]]

[,1] [1,] 28371.69

```
[2,] 56743.39
[3,] 85115.08
[4,] 113486.78
stage 1 for RA7
sampleSizeResultGS7[["numberOfSubjects1"]]
 [,1]
[1,] 14185.85
[2,] 28371.69
[3,] 42557.54
[4,] 56743.39
data_stage1d7 <- data1[1:14186,]
meand7stage1 <-apply(data_stage1d7[,c("retention_7_t","retention_7_c")],2,mean)</pre>
rate7_1.t <- meand7stage1[1]</pre>
rate7_1.c <- meand7stage1[2]</pre>
staystage1_t7 <- sum(data_stage1d7$retention_7_t)
staystage1_c7 <- sum(data_stage1d7$retention_7_c)</pre>
sizestage1.7 <- nrow(data_stage1d7)</pre>
d7ra.stage1 <- (staystage1_c7+staystage1_t7)/(2*sizestage1.7)
se.71 <- sqrt(d7ra.stage1*(1 - d7ra.stage1)*(1/sizestage1.7+1/sizestage1.7))
z.value.71 <- (rate7_1.t - rate7_1.c)/se.71
unname(z.value.71)
[1] 1.383307
#stage 2 for RA7
data_stage1d7 <- data1[1:28372,]
meand7stage1 <-apply(data_stage1d7[,c("retention_7_t","retention_7_c")],2,mean)</pre>
rate7_1.t <- meand7stage1[1]</pre>
rate7_1.c <- meand7stage1[2]</pre>
staystage1_t7 <- sum(data_stage1d7$retention_7_t)</pre>
staystage1_c7 <- sum(data_stage1d7$retention_7_c)</pre>
sizestage1.7 <- nrow(data_stage1d7)</pre>
d7ra.stage1 <- (staystage1_c7+staystage1_t7)/(2*sizestage1.7)</pre>
se.71 <- sqrt(d7ra.stage1*(1 - d7ra.stage1)*(1/sizestage1.7+1/sizestage1.7))
z.value.71 <- (rate7_1.t - rate7_1.c)/se.71
unname(z.value.71)
```

[1] 2.763375

```
#stage 3 for RA7
data_stage1d7 <- data1[1:42558,]
meand7stage1 <-apply(data_stage1d7[,c("retention_7_t","retention_7_c")],2,mean)
rate7_1.t <- meand7stage1[1]
rate7_1.c <- meand7stage1[2]
staystage1_t7 <- sum(data_stage1d7$retention_7_t)
staystage1_c7 <- sum(data_stage1d7$retention_7_c)
sizestage1.7 <- nrow(data_stage1d7)
d7ra.stage1 <- (staystage1_c7+staystage1_t7)/(2*sizestage1.7)
se.71 <- sqrt(d7ra.stage1*(1 - d7ra.stage1)*(1/sizestage1.7+1/sizestage1.7))
z.value.71 <- (rate7_1.t - rate7_1.c)/se.71
unname(z.value.71)</pre>
```

[1] 2.621098

```
(87212-85116)/87212
```

[1] 0.02403339

Sample size calculation for a binary endpoint

Sequential analysis with a maximum of 5 looks (group sequential design), overall significance level 5% (two-sided). The results were calculated for a two-sample test for rates (normal approximation), H0: pi(1) - pi(2) = 0, H1: treatment rate pi(1) = 0.19, control rate pi(2) = 0.183, power 80%.

Stage	1	2	3	4	5
Planned information rate	20%	40%	60%	80%	100%
Efficacy boundary (z-value	4.877	3.357	2.680	2.290	2.031
scale) Futility boundary (z-value scale)		0.486	1.048	1.556	
Cumulative power	0.0002	0.0792	0.3855	0.6749	0.8000
Number of subjects	21046.4	42092.8	63139.2	84185.6	105232.0
Expected number of subjects under H1	74013.4				
Cumulative alpha spent	< 0.0001	0.0008	0.0076	0.0244	0.0500
Cumulative beta spent	0	0.0646	0.1173	0.1616	0.2000
Two-sided local significance level	< 0.0001	0.0008	0.0074	0.0220	0.0423
Lower futility boundary (t)		-0.002	-0.003	-0.004	
Upper futility boundary (t)		0.002	0.003	0.004	
Overall exit probability (under H0)	< 0.0001	0.3740	0.3730	0.1789	
Overall exit probability (under H1)	0.0002	0.1436	0.3589	0.3338	

Stage	1	2	3	4	5
Exit probability for efficacy (under H0)	<0.0001	0.0008	0.0068	0.0160	
Exit probability for efficacy (under H1)	0.0002	0.0789	0.3063	0.2894	
Exit probability for futility (under H0)	0	0.3732	0.3661	0.1629	
Exit probability for futility (under H1)	0	0.0646	0.0526	0.0444	

#### Legend:

• (t): treatment effect scale

```
data_stage1d7 <- data1[1:31570,]
meand7stage1 <-apply(data_stage1d7[,c("retention_7_t","retention_7_c")],2,mean)
rate7_1.t <- meand7stage1[1]
rate7_1.c <- meand7stage1[2]
staystage1_t7 <- sum(data_stage1d7$retention_7_t)
staystage1_c7 <- sum(data_stage1d7$retention_7_c)
sizestage1.7 <- nrow(data_stage1d7)
d7ra.stage1 <- (staystage1_c7+staystage1_t7)/(2*sizestage1.7)
se.71 <- sqrt(d7ra.stage1*(1 - d7ra.stage1)*(1/sizestage1.7+1/sizestage1.7))
z.value.71 <- (rate7_1.t - rate7_1.c)/se.71
unname(z.value.71)</pre>
```

[1] 2.985519

```
63140/2
```

[1] 31570

## (87212-63140)/87212

[1] 0.2760171

sampleSizeResultGS7[["expectedNumberOfSubjectsH1"]]# compare ASN under H1

[1] 74013.43

sampleSizeResultGS7[["maxNumberOfSubjects"]]

[1] 105232

(105232-87212)/87212

[1] 0.2066229