

Adaptive Methods in Clinical Research

Practical 2 Solutions: Group Sequential Designs

Q1

```
> power.t.test(delta = 0.5, type = "two.sample", alternative = "one.sided",
, power = 0.9)

Two-sample t test power calculation

      n = 69.19782
    delta = 0.5
      sd = 1
sig.level = 0.05
  power = 0.9
alternative = one.sided

NOTE: n is number in *each* group
```

Q3

- a) 138.971
- b) 137.745
- c) 112.13
- d) 0.009
- e) 0.386

Q4

- a) 152.022
- b) 147.412
- c) 104.934
- d) 0.03
- e) 0.62

Q5

ESS for null-optimal design under the null = 95.579

ESS for alternative-optimal design under the alternative = 104.447

Q6

Maximum sample size increases, ESS under the null increases, ESS under the alternative decreases

Diminishing returns as number of stages increases

Q7

Larger maximum sample size and ESS *but* many more patients given the experimental treatment and lower median sample size.

This may be a preferred approach if there is a strong ethical (patient benefit) rationale to give experimental treatment.