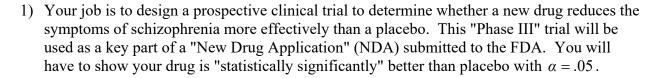
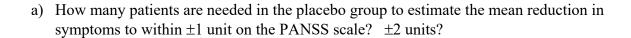
## Biostatistics 140.623 Third Term, 2017-2018

## **Laboratory Exercise 1**



The usual design is to measure the change in PANSS (Positive + Negative Symptoms of Schizophrenia) score (higher is worse symptoms) from baseline to 8 weeks after start of treatment. In past studies with similar patients, the average (std dev) change for placebo as -10 (10) units. You expect the new drug will reduce symptoms by an average value of -12 to -16 units and have a similar standard deviation to that observed for placebo.



b) How many patients are needed in each group to estimate the difference in change between the new drug and placebo groups to within ±1 unit on the PANSS scale? ±2 units?

Biostatistics 140.623 Laboratory Exercise 1

c) Design a table to show the sample size per group necessary to obtain 90% power to reject the null hypothesis that the two groups have equivalent changes in average PANSS score using a significance level of 0.05. Vary the true difference among 1, 2, and 5 units; vary the standard deviation of a person's change between 10 and 12 units.

True Difference	Standard Deviation	Sample Size per Group

d) How might this table be altered to take account of other important events that commonly occur in clinical trials?

2

Biostatistics 140.623 Laboratory Exercise 1

```
. sampsi 0 1 , p(0.9) r(1) sd1(10) sd2(10)
Estimated sample size for two-sample comparison of means
Test Ho: m1 = m2, where m1 is the mean in population 1
                   and m2 is the mean in population 2
Assumptions:
        alpha = 0.0500 (two-sided)
        power =
                  0.9000
           m1 =
                       0
           m2 =
                       1
          sd1 =
                      10
           sd2 =
                      10
        n2/n1 =
                    1.00
Estimated required sample sizes:
            n1 =
                    2102
           n2 =
                    2102
. sampsi 0 1 , p(0.9) r(1) sd1(12) sd2(12)
Estimated sample size for two-sample comparison of means
Test Ho: m1 = m2, where m1 is the mean in population 1
                   and m2 is the mean in population 2
Assumptions:
        alpha =
                  0.0500 (two-sided)
        power =
                 0.9000
           m1 =
                      0
           m2 =
                       1
           sd1 =
                      12
          sd2 =
                      12
        n2/n1 =
                    1.00
Estimated required sample sizes:
                    3027
            n2 =
                    3027
. sampsi 0 2 , p(0.9) r(1) sd1(10) sd2(10)
Estimated sample size for two-sample comparison of means
Test Ho: m1 = m2, where m1 is the mean in population 1
                   and m2 is the mean in population 2
Assumptions:
        alpha = 0.0500 (two-sided)
        power =
                 0.9000
           m1 =
                       0
           m2 =
                       2
          sd1 =
                      10
          sd2 =
                      10
        n2/n1 =
                    1.00
Estimated required sample sizes:
            n1 =
                      526
            n2 =
                      526
```

Biostatistics 140.623 Laboratory Exercise 1

```
. sampsi 0 2 , p(0.9) r(1) sd1(12) sd2(12)
```

Estimated sample size for two-sample comparison of means Test Ho: m1 = m2, where m1 is the mean in population 1 and m2 is the mean in population 2

Assumptions:

```
alpha = 0.0500 (two-sided)
power = 0.9000
    m1 = 0
    m2 = 2
    sd1 = 12
    sd2 = 12
n2/n1 = 1.00
```

Estimated required sample sizes:

```
n1 = 757
n2 = 757
```

```
. sampsi 0 5 , p(0.9) r(1) sd1(10) sd2(10)
```

Estimated sample size for two-sample comparison of means
Test Ho: m1 = m2, where m1 is the mean in population 1
and m2 is the mean in population 2

Assumptions:

```
alpha = 0.0500 (two-sided)
power = 0.9000
m1 = 0
m2 = 5
sd1 = 10
sd2 = 10
n2/n1 = 1.00
```

Estimated required sample sizes:

```
n1 = 85
n2 = 85
```

```
. sampsi 0 5 , p(0.9) r(1) sd1(12) sd2(12)
```

Estimated sample size for two-sample comparison of means
Test Ho: m1 = m2, where m1 is the mean in population 1
and m2 is the mean in population 2

Assumptions:

```
alpha = 0.0500 (two-sided)
power = 0.9000
  m1 = 0
  m2 = 5
  sd1 = 12
  sd2 = 12
  n2/n1 = 1.00
```

Estimated required sample sizes:

```
n1 = 122
n2 = 122
```