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### **Appendix 1**

An Algorithm was developed in R to simulate PROMs at Baseline and Follow Up and illustrate how a portion of patients having a significant effect can hide poorer outcomes of the rest of the cohort. The input is: number of patients having an effect from a procedure, mean and standard deviation at both Baseline and Follow up. The algorithm then calculates the number of patients having no effect (the same score at Baseline and Follow up, which it draws from the pool of Baseline scores) which can be part of the cohort until 1. p-value  $<.05$  is overturned and 2. Mean difference between Baseline and Follow Up is  $> MCID$ .

```
numOrigValues = 75
```

```
meanDF1 = 37
```

```
meanDF2 = 84
```

```
MCID = meanDF2 - meanDF1
```

```
timeZeroDF = rnorm(numOrigValues, mean = meanDF1, sd = 8)
```

```
timeTwelveDF = rnorm(numOrigValues, mean = meanDF2, sd = 12)
```

```
CalculationDF = data.frame(mean1 = mean(timeZeroDF), sd1 = sd(timeZeroDF), n1 =  
length(timeZeroDF),
```

```
mean2 = mean(timeTwelveDF), sd2 = sd(timeTwelveDF), n2 = length(timeTwelveDF),
```

```
MCID = MCID,
```

```
p_value = t.test(timeZeroDF, timeTwelveDF, paired = TRUE, alternative =  
"two.sided")$p.value)
```

```
x = 1
```

```
while (CalculationDF$p_value[x] <= 0.05)
```

```
{
```

```
  x = x + 1
```

```
  CalculationDF[nrow(CalculationDF) + 1,] = c(0, 0, 0, 0, 0, MCID, 0)
```

```
  timeZeroDF = append(timeZeroDF, sample(timeZeroDF, 1))
```

```
  timeTwelveDF = append(timeTwelveDF, sample(timeZeroDF, 1))
```

```
  CalculationDF$mean1[x] = mean(timeZeroDF)
```

```
  CalculationDF$sd1[x] = sd(timeZeroDF)
```

```
  CalculationDF$n1[x] = length(timeZeroDF) - numOrigValues
```