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Non-Inferiority Goal - Continuous Endpoint

- **N per group = $16 \times (SD/D)^2$**
 - ◆ **Where D = maximum allowable difference**
- **Example**
 - ◆ **Expect bone mineral density of 0.999g/cm²**
 - ◆ **Know that standard deviation (SD) in bone mineral density is approximately 0.01g/cm² from the literature**
 - ◆ **Can allow new treatment to result in difference in bone mineral density no larger than .009g/cm²**
 - ◆ **$N = 16 \times (0.01/0.009)^2$**
 - ◆ **$N = 19.75$**
 - ◆ **20 patients per group are required for this study**