2. *Suppose* you could redesign the study as a clinical trial. (Assume ethical considerations, such as beneficence, have already been addressed.) One of the first things you would need to do is **determine how many people to study**. [You may want to review the sample size lessons in Chapter 16 and Lab 6 before proceeding.] Things you must consider are: a) the *alpha* level you want for your study, b) the level of *power* you want, c) the *llocation ratio* of sample sizes (n_1 / n_0), d) the *background risk* (p_0), and e) the *elevation in risk* you want to detect (by providing either p_1 or the expected risk ratio). Let us start by assuming a baseline risk of 10% (i.e., .10), n_1 / n_0 = 1, and α = .05 (two-sided). Determine the total sample size (both groups combined) for the detectable risk ratios and powers listed below. Use the regular (*NOT* continuity corrected) required sample sizes calculated by COMPARE2.EXE > Sample Size. Fill in this table:

	Detectable risk ratio			
Power	1.5	2.0	4.0	6.0
.80				
.90				
.95				

a) How does *lowering the expected elevation in risk* effect your sample size requirements?

b) How does *increasing the desired power* of the study effect your sample size requirements?

Next, **randomize** the exposure (treatment) into two groups. Assuming 80% power, alpha = .05 (two-sided), background risk of .1, and an expected risk ratio of 6.0, N = 28 (i.e., 14 in each group). Study subjects are labeled 1, 2, . . . 28. Use www.random.org and generate a **randomized sequence** (without duplicates) of 28 numbers. The first 14 will comprise the treatment group (generic formuluation) and the remainder will be the control group. List the study groups:

Treatment group IDs (exposed to generic formulation)

Control group IDs (exposed to innovator formulation)

c) On an attachment (or back of this page), **describe the primary benefit of randomization**.