FROM NON-INFERIORITY TO SUPERIORITY

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The CPMP document "Points to Consider on Switching between Superiority and Noninferiority" gives an excellent account on the issues of testing non-inferiority and superiority in clinical trials. When the test result of non-inferiority is positive, one can go on testing for superiority also without any penalty to the type I error rate. It states that: "There is no multiplicity argument that affects this interpretation because, in statistical terms, it corresponds to a simple closed test procedure."

It implicitly implies that both non-inferiority and superiority are to be tested at the same significance level α. However, mathematically it does not need to be so. This short note gives a sufficient condition for both tests to maintain its own α without multiplicity adjustment when the test statistic is normally distributed. Furthermore, one can start from superiority test first, and then switch to testing non-inferiority if the former is not significant. Statistically, there is no difference from the more conventional process of switching from non-inferiority to superiority.