# CONSIDERATIONS FOR THE DESIGN OF CLINICAL TRIALS FOR TINNITUS

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We review several issues related to the implementation of clinical trials for tinnitus. A double-blind randomized cross-over design is usually the most robust. However crossover designs are difficult if the tinnitus is permanently cured or decreased or if the duration (washout period) of a temporary effect is unknown. Primary and secondary measurements should be carefully chosen depending on whether the intent is to reduce the magnitude of the tinnitus or to alleviate some of its symptoms. Secondary measures should include duration of tinnitus, cause of tinnitus and/or associated hearing loss, and magnitude of tinnitus and hearing loss. Several good handicap questionnaires are available. As regards to the scaling of responses on such questionnaires, we believe 100-point interval scaling is advantageous by allowing a free range of scoring. Ordinal scales (good, better, best) are to be avoided as the intervals between labels maybe be very non-linear. We also discuss issues related to drop-outs, subject self-selection bias, and clinical versus statistical significance.