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Reflecting the vast research on

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explains how to choose the NI margin as a small fraction of the therapeutic effect of the active control in a clinical trial.

Requiring no prior knowledge of NI testing, the book is easily accessible to both statisticians and nonstatisticians

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involved in drug development.

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In an equivalence trial, the statistical test aims at showing that two treatments are not too different in characteristics, where "not too different" is defined in a clinical manner. Finally, in

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a non-inferiority trial, the aim is to show that an experimental treatment is not (much) worse than a standard treatment.

Superiority, equivalence, and non-inferiority trials

Take Your NI Trial to the Next Level

Reflecting the vast research on

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noninferiority (NI) designs from the past 15 years, Noninferiority Testing in Clinical Trials: Issues and Challenges explains how to choose the NI margin as a small fraction of the therapeutic effect of the active control in a clinical trial.

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**Noninferiority Testing in Clinical
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Indeed, the ICH guidance (ref 1) requires that the non-inferiority margin is specified in the clinical trial protocol. Setting a non-inferiority margin objectively can be done by thinking carefully about what it means for

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What is a Non-inferiority Clinical Trial? - Quantics ...

Non-Inferiority Clinical Trials to Establish Effectiveness . Guidance for Industry. 1. This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this...

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**Non-Inferiority Clinical Trials to
Establish Effectiveness ...**

This document provides guidance to sponsors and applicants submitting investigational drug applications (INDs), new drug applications (NDAs), biologics licensing applications (BLAs), or...

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Non-Inferiority Clinical Trials | FDA

Noninferiority clinical trials have become a major tool for the evaluation of drugs, devices, biologics, and other medical treatments.

Challenges in the Design and Interpretation of ...

Non-inferiority studies are used to show

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that a minimum level of efficacy has been achieved. In comparison studies with a current therapy, non-inferiority is used to demonstrate that the new therapy provides at least the same benefit to the patient. Superiority trials are always used when comparisons are made to placebo or vehicle treatments.

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Trial Designs—Non-inferiority vs. Superiority vs ...

Clinical trials traditionally aim to show a new treatment is superior to placebo or standard treatment, that is, superiority trials. There is an increasing number of trials demonstrating a new treatment is non-inferior to standard treatment. The hypotheses, design and interpretation of

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**Non-inferiority trials in cardiology:
what clinicians need ...**

The Investigators will conduct two parallel, individually randomized, double blind non-inferiority trials in India and Tanzania. Participating pregnant woman

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will be randomized to either 1500 mg or 500 mg calcium supplementation. The India and Tanzania trials are independently powered for the primary outcomes of i) preeclampsia and ii) preterm ...

Non-inferiority of Lower Dose Calcium Supplementation ...

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The terms superiority, equivalence and non-inferiority are used frequently in publications on clinical trials. To someone starting out in clinical research these three terms and their precise meaning can be quite difficult to grasp. Indeed even experienced researchers have trouble getting their head around these hypotheses.

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What is the difference between Superiority vs. Equivalence ...

If all the design features are similar except the patient characteristics the estimate of the size of the control effect can be adjusted if the effect size is known in the patient sub-groups.

Benefits of non-inferiority trials. A non-

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inferiority trial is useful when a placebo
controlled trial is not appropriate.

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FDA Guidance on Non-Inferiority Clinical Trials to ...

In contrast, the main objective of non-licencing trials is to publish information that allows other bodies (commissioners of health services, producers of clinical

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guidelines, etc.) to make considered
decisions about which treatments should
be funded or recommended.

Superiority and non-inferiority: two sides of the ... - Trials

Testing the non-inferiority hypothesis

Non-inferiority trials are conducted to show that an experimental treatment is

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not worse than the control by a predefined non-inferiority margin in terms of the primary outcome (the alternative hypothesis, H_1).

Non-adherence in non-inferiority trials: pitfalls and ...

When data from trials designed to show superiority of a test product over

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placebo are being interpreted, an informal two-stage procedure is employed involving the consideration of both statistical significance and clinical relevance. The same two-stage procedure can be used for interpreting non-inferiority trials.

Guideline on Non-inferiority Margin

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For instance, clinical trials in acute bacterial sinusitis, acute otitis media, and acute exacerbations of chronic obstructive pulmonary disease routinely show “noninferiority” of one antimicrobial to another, yet the effects of the control drug compared with placebo are unclear in these diseases. 40-42 It is insufficient to merely know

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that a control intervention “works.”
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