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## **The myths of clinical trials**

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## Myths of clinical trials

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Generation time and date: (Thursday 9:53am) 26 June 2003; Location: \Myths

## **Myth**

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A popular belief that is false or baseless

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\Myths\Myth

## **Myth**

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That being in a trial is akin to being a guinea pigs

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\Myths\GuineaP

## **Myth**

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Only those receiving the test treatment will benefit

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\Myths\TestTrt

## **Myth**

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That placebos have no effects

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\Myths\Placebo

## **Myth**

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That people enroll in trials because they expect to benefit

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\Myths\ParTake

## **Myth**

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That trials have concentrated on men and their diseases  
to the exclusion of women and their disease

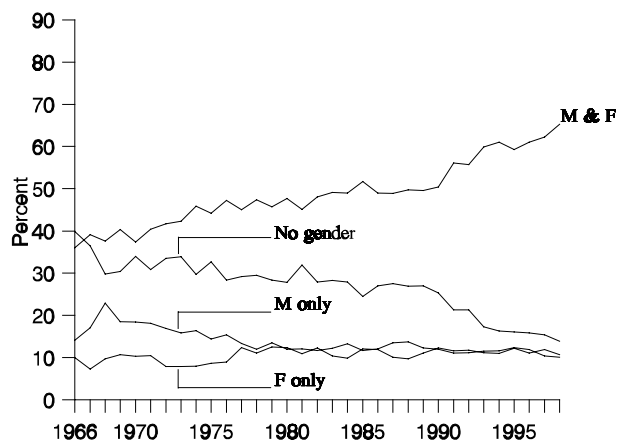
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\Myths\Women

## Myths of clinical trials

### Published trials by gender

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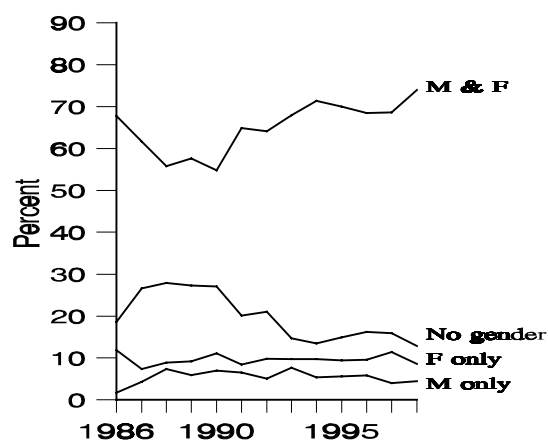



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\\Myths\Gender.Plt

### Published multicenter trials by gender

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\\Myths\MCT.Plt

## Myths of clinical trials

### Myth

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That selection bias matters

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\Myths\SelBias

### Myth

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That "representativeness" is possible

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\Myths\RepPoss

### Myth

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That validity depends on "representativeness"

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\Myths\Valid

### Myth

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That generalization depends on "representativeness"

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\Myths\General

### Myth

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That randomization ensures comparability

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\Myths\Random

### Myth

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That data can be spoiled by looking at them

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\Myths\Spoil

### Myth

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That p-values indicate significance

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\Myths\Pvalue

## Myths of clinical trials

### Myth

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That subgroup analysis is a sin

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\Myths\Subgroup

### Myth

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That masked trials are better than unmasked trials

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\Myths\Masking

### Myth

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That the monitoring body should be isolated from study investigators

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\Myths\Independ

### Myth

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That monitoring bodies should be masked

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\Myths\MaskTEM

### Myth

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That monitoring must be according to pre-ordained stopping rules

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\Myths\StopRule

### Myth

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That truth can be revealed by a single trial

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\Myths\Truth

### Myth

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That investigators are not to be trusted

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\Myths\Trust

## Myths of clinical trials

### Myth

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That anybody can do a trial

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\Myths\Anybody

### Myth

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That trials change the practice of medicine

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\Myths\Impact

### Myth

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That a trialist is merely an epidemiologists who randomizes

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\Myths\EpiCT

### Epidemiology

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A branch of medical science that deals with the incidence, distribution, and control of a disease in a population (Merriam Webster's *10th Collegiate Dictionary* 2001)

The study of the distribution and determinants of health-related states or events in specified populations, and the application of this study to control of health problems (Last's *Dictionary of Epidemiology*, 4<sup>th</sup> ed, 2001)

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\EpiVsCT\EpiDefn

### The epidemiologist vs the trialist

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- The epidemiologist is concerned with causality; the trialist with determining whether a treatment works
  - The epidemiologist is an observationist; the trialist is an interventionist
  - The epidemiologist is an "absolutist"; the trialist is a relativist
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\EpiVsCT\Trialist



## Myths of clinical trials

### **Toward a broader definition of epidemiology**

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An observational and evaluative (experimental and intervention) medical science concerned with the cure, prevention, amelioration, or elimination of disease and related adverse health conditions by study of the patterns and distribution of disease and related adverse health conditions to determine source and cause and by study to assess the relative merit of different control or treatment procedures.

Or Last rewritten

The study of the distribution and determinants of health-related states or events in specified populations *through observation, intervention, or experimentation*, and the application of this study to control of health problems

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\EpiVsCT\NewDefn