

## Titre de l'article

How to evaluate the efficacy of a new drug?

## Auteur(s)

Berbis J<sup>a</sup>, Alessandrini M<sup>a</sup>, Karsenty G<sup>b,c</sup>, Auquier P<sup>a</sup>.

## Affiliation(s) du ou des auteurs

<sup>a</sup> EA 3279 santé publique et maladies chroniques, faculté de médecine, Aix-Marseille université, 27, boulevard Jean-Moulin, 13385 Marseille cedex 05, France

<sup>b</sup> Aix-Marseille université, 13284 Marseille, France

<sup>c</sup> Urologie et transplantation rénale, hôpital de La Conception, AP-HM, 147, boulevard Baille, 13385 Marseille cedex 05, France

## Résumé

### AIM:

To give a practical guide for phase III clinical trial reading in order to evaluate independently the efficacy of a (new) drug therapy.

### METHOD:

Synthesis established by public health teachers and illustrated with examples in the field of urology.

### RESULTS:

A structured and simplified critical review of clinical trial remains the main way to "have an idea" of a new drug efficacy. Efficacy in clinical trial may be far from patient satisfaction, willingness to pursue with this treatment or cost-effectiveness relevance.

### CONCLUSION:

Knowledge of patient expectation, disease evolution and epidemiology have to be put side by side to raw efficacy data coming from phase III study in order to evaluate efficiency and effectiveness of new drugs therapy.

## Mots-clés

Clinical trial ; Critère de jugement ; Efficacité ; Efficacy ; Efficience; Efficiency ; Essai clinique ; Primary outcome ; Randomisation.

## Revue

*Progrès en Urologie*

## Source

*Progrès en Urologie*, Volume 23, Issue 15, November 2013, Pages 1208–1212, Rapport AFU 2013. Le médicament en urologie

## Editeur

Elsevier

## Lien

<http://www.sciencedirect.com/science/article/pii/S1166708713007057>