

Project Rebuild the Evidence Base (REB): a method to interpret randomised clinical trials and their meta-analysis to present solid benefit-risk assessments to patients.

Rémy Boussageon¹, Clara Blanchard², Elodie Charuel³, Thibault Menini³, Bruno Pereira⁴, Florian Naudet⁴, Behrouz Kassai⁵, François Gueyffier⁶, Michel Cucherat⁴, and Hélène Vaillant-Roussel³

¹Université Claude Bernard Lyon 1

²University of Poitiers

³Clermont Auvergne University

⁴University Hospital Centre Clermont-Ferrand

⁵Université Claude Bernard Lyon 1

⁶Centre Hospitalier Universitaire de Lyon

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Abstract

Introduction: Evidence-based medicine is the cornerstone of shared-decision making in healthcare today. The public deserves clear, transparent and trust-worthy information on drug efficacy. Yet today, many drugs are prescribed and used without solid evidence of efficacy. Moreover, meta-analyses are the staple to test for drug efficacy and adverse effects, but spins can lead to unconvincing conclusions. In a shared medical decision-making approach, general practitioners need drug assessment to be based on patient-important outcomes. The aim of project Rebuild the Evidence Base (REB) is to bridge the gap between the data needed in clinical practice and the data available from clinical research. **Methods and Analysis:** The drugs will be assessed on clinical patient important outcomes and for a population. Using the Cochrane tools, we propose to analyse for each population and outcome : 1) a meta-analysis, based on randomised controlled trials (RCTs) with low risk of bias overall ; 2) Confirmatory RCT with low risk of bias overall; 3) Heterogeneity between RCT, and 4) Publication bias assessment. Depending on the results of these analyses, evidence would be rated according to 4 levels: firm evidence, evidence, results to be confirmed (but no evidence) or lack of evidence. **Conclusion:** Project REB proposes a method for reading and interpreting randomized clinical trials and their meta-analysis to produce quality data for general practitioners to focus on benefit-risk assessment in the interest of patients. If this data does not exist, it could enable clinical research to better its aim.

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