

REVIEW

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# Drug safety assessment in clinical trials: methodological challenges and opportunities

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## Abstract

Randomized controlled trials are the principal means of establishing the efficacy of drugs. However pre-marketing trials are limited in size and duration and exclude high-risk populations. They have limited statistical power to detect rare but potentially serious adverse events in real-world patients. We summarize the principal methodological challenges in the reporting, analysis and interpretation of safety data in clinical trials using recent examples from systematic reviews. These challenges include the lack of an evidentiary gold standard, the limited statistical power of randomized controlled trials and resulting type 2 error, the lack of adequate ascertainment of adverse events and limited generalizability of trials that exclude high risk patients. We discuss potential solutions to these challenges. Evaluation of drug safety requires careful examination of data from heterogeneous sources. Meta-analyses of drug safety should include appropriate statistical methods and assess the optimal information size to avoid type 2 errors. They should evaluate outcome reporting biases and missing data to ensure reliable and accurate interpretation of findings. Regulatory and academic partnerships should be fostered to provide an independent and transparent evaluation of drug safety.

## Review

### Background

Randomized controlled trials are primarily designed to provide reliable information on the efficacy of interventions [1]. They form the primary basis of regulatory approval for a drug in the US, which involves demonstrating evidence of efficacy and safety in two well-conducted studies. With rare exceptions, these are generally interpreted as statistically significant data from two randomized clinical trials. Several advances have been made in the approach to the conduct, analysis and interpretation of data from randomized controlled trials on efficacy outcomes [1].

Since trials are typically carried out to define therapeutic benefit for regulatory approval, safety receives less attention [2]. The role of drug safety regulation is to protect patients from rare, severe adverse reactions; most efforts are directed at early detection and prevention of serious events such as that seen with thalidomide. Post-marketing surveillance through spontaneous adverse event reporting systems are the mainstay of drug

safety evaluation. Methodological issues around the analysis of safety data from clinical trials have received less attention.

Systematic reviews and meta-analyses of clinical trials have recently raised concerns about an increase in the risk of serious adverse cardiovascular outcomes associated with varenicline [2-4], an increased risk of mortality associated with the tiotropium Respimat inhaler, and adverse cardiovascular outcomes associated with inhaled anticholinergics (including the ipratropium and tiotropium inhaler) [5,6]. Similarly, increased risks of myocardial infarction associated with rosiglitazone [7-9] and congestive heart failure and fractures associated with the thiazolidinediones (rosiglitazone and pioglitazone) in clinical trials have resulted in regulatory warnings [10,11]. These findings have been widely debated with conflicting interpretation by the academic community, regulators and industry sponsors [12-14]. Regulators have emphasized the limitations to defining and measuring adverse outcomes in randomized controlled trials and have called for caution in drawing any robust conclusions [12]. The lack of access to individual participant data, the heterogeneous nature of safety data, and the statistical challenges of analyzing rare events make safety data from such meta-analyses difficult to analyze and

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# Drug Safety Assessment In Clinical Trials

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