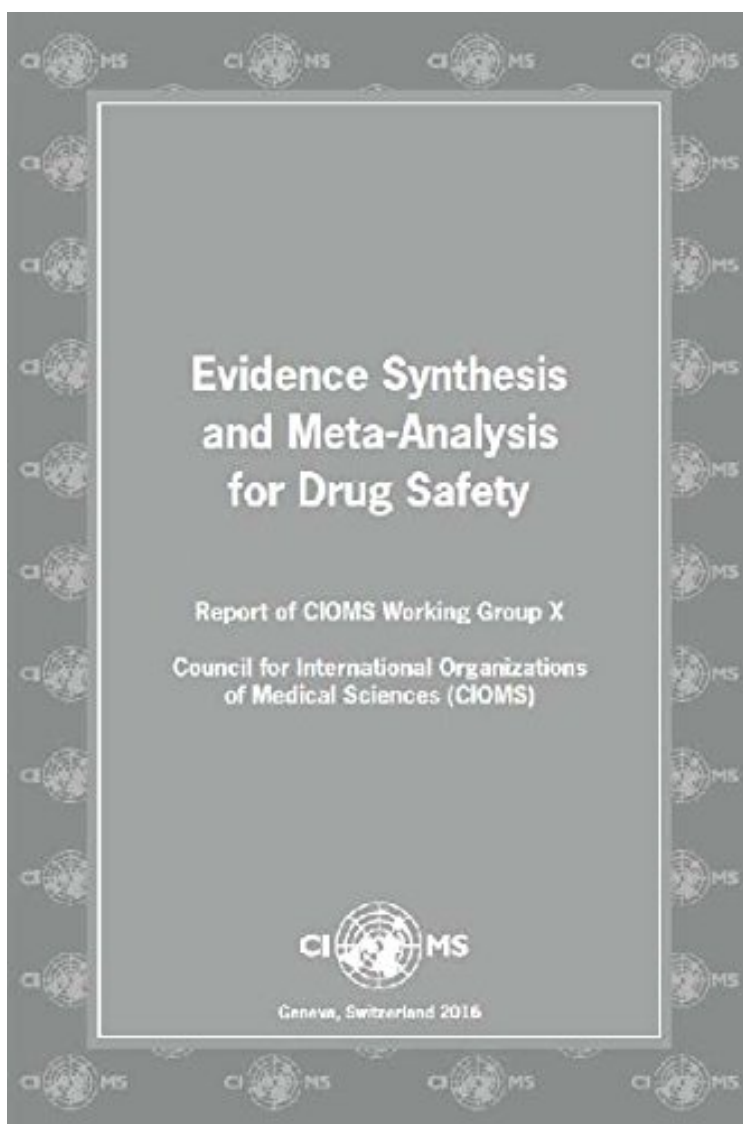


[Library ebook] Evidence Synthesis and Meta-Analysis for Drug Safety: Report of CIOMS Working Group X (A CIOMS Publication)

## Evidence Synthesis and Meta-Analysis for Drug Safety: Report of CIOMS Working Group X (A CIOMS Publication)

*Council for International Organizations of Medical Sciences (CIOMS)*  
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**Council for International Organizations of Medical Sciences (CIOMS) : Evidence Synthesis and Meta-Analysis for Drug Safety: Report of CIOMS Working Group X (A CIOMS Publication)** before purchasing it in order to gage whether or not it would be worth my time, and all praised Evidence Synthesis and Meta-Analysis for Drug

At any point in the drug development process, systematic reviews and meta-analysis can provide important information to guide the future path of the development program and any actions that might be needed in the post-marketing setting. This report gives the rationale for why and when a meta-analysis should be considered, all in the context of regulatory decision-making, and the tasks, data collection, and analyses that need to be carried out to inform those decisions. There is increasing demand by decision-makers in health care, the bio-pharmaceutical industry, and society at large to have access to the best available evidence on benefits and risks of medicinal products. The best strategy will take an overview of all the evidence and where it is possible and sensible, combine the evidence and summarize the results. For efficacy, the outcomes generally use the same or very similar predefined events for each of the trials to be included. Most regulatory guidance and many Cochrane Collaboration reviews have usually given more attention to assessment of benefits, while issues around combining evidence on harms have not been as well-covered. However, the (inevitably) unplanned nature of the data on safety makes the process more difficult. Combining evidence on adverse events (AEs), where these were not the focus of the original studies, is more challenging than combining evidence on pre-specified benefits. This focus on AEs represents the main contribution of the current CIOMS X report. The goal of the CIOMS X report is to provide principles on appropriate application of meta-analysis in assessing safety of pharmaceutical products to inform regulatory decision-making. This report is about meta-analysis in this narrow area, but the present report should also provide conceptually helpful points to consider for a wider range of applications, such as vaccines, medical devices, veterinary medicines or even products that are combinations of medicinal products and medical devices. Although some of the content of this report describes highly technical statistical concepts and methods (in particular Chapter 4), the ambition of the working group has been to make it comprehensible to non-statisticians for its use in clinical epidemiology and regulatory science. To that end, Chapters 3 and 4, which contain the main technical statistical aspects of the appropriate design, analysis and reporting of a meta-analysis of safety data are followed by Chapter 5 with a thought process for evaluating the findings of a meta-analysis and how to communicate these.

About the Author Council for International Organizations of Medical Sciences (CIOMS) is an international, non-governmental, non-profit organization established jointly by WHO and UNESCO in 1949. In 2009 CIOMS celebrated the 60th anniversary of its creation. Through its membership, CIOMS is representative of a substantial proportion of the biomedical scientific community. In 2013, the membership of CIOMS included 49 international, national and associate member organizations, representing many of the biomedical disciplines, national academies of sciences and medical research councils.