

# **Vulnerabilità e *bias* di genere nella ricerca clinica: implicazioni etiche e metodologiche**

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## *Vulnerability and Gender Bias in Clinical Research: A Review of Ethical and Methodological Implications*

*Abstract:* Debates around the so-called “sex bias” in clinical research have gained considerable traction within contemporary health research and its attending ethical and socio-political reflection. Scientific advances have led to the discovery of significant biological differences between men and women. Yet, a comprehensive consideration of sex as a relevant variable in clinical research is, from the most part, still lacking. This article conducts a narrative review of published literature to map the ethical and methodological implications of sex bias in clinical research. Its findings point to a multidimensional understanding of such issue, which unfolds throughout the entire spectrum of clinical research, from data collection through to data analysis, interpretation, and reporting. In outlining the evolution of normative guidance and policy documents on this issue, we trace a conceptual shift from protection-through-exclusion of women framed as (potentially) vulnerable research subjects towards an approach highlighting the benefits of inclusion deriving from their heightened participation in clinical research. Yet, notwithstanding Italy’s leading role in Europe in enacting policies to tackle sex bias in research, the latter is far from being satisfactorily addressed.

*Keywords:* Gender bias, Clinical trials, Ethics, Vulnerability.

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