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Short summary

This paper discusses the need for a framework to assess the trustworthiness of new biostatistical methods before they can be safely used in data analyses. Similar to the phases of clinical research in drug development, the authors propose four phases of methodological research. While in phase I typically a new methodological idea is proposed and mathematically described, phases II – IV mainly deal with its evaluation. More specifically, phase II typically studies its performance with limited simulations, phase III provides neutral head-to-head comparisons to other established methods in a wide range of scenarios, and phase IV aims at clarifying implicit assumptions of a method and diagnostics such that the method can be safely used in practice also in very specific or unusual applications. The paper emphasizes the importance of studies in phases III and IV to explore the empirical properties of existing methods and promote reproducibility in biostatistics research.