Use of extrapolation common in FDA new drug approvals

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Extrapolation from pivotal trial data to broader U.S. Food and Drug

Administration (FDA)-approved indications is common, according to a study published online April 19 in *JAMA Network Open*.

Daniel Feldman, M.P.H., from Brigham and Women's Hospital in Boston, and colleagues examined the frequency of extrapolation of clinical characteristics beyond pivotal trial data to the final approved indication. Analysis included 105 novel FDA drug approvals from 2015 to 2017.

The researchers found that 23 extrapolations of study population characteristics from clinical trials to the approved indication were identified in 21 drugs (20 percent) overall. It was most common for extrapolation of trial findings to occur for patients with greater disease severity (14 drugs), followed by differences in disease subtype (six drugs) and concomitant medication use (three drugs).

"The findings of this study suggest that extrapolation from pivotal trial data to FDA-approved indications is common," the authors write. "Although extrapolations may be grounded in reasonable clinical predictions, they can limit the generalizability of such indications to specific prescribing decisions; these findings suggest a greater need for close postapproval monitoring to determine whether new safety issues arise, or effectiveness differs from expectations when these medications are used in broader real-world populations."

More information: Abstract/Full Text
Editorial

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