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Consensus statement

# Interpreting the Clinical Importance of Treatment Outcomes in Chronic Pain Clinical Trials: IMMPACT Recommendations

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### Abstract

A consensus meeting was convened by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) to provide recommendations for interpreting clinical importance of treatment outcomes in clinical trials of the efficacy and effectiveness of chronic pain treatments. A group of 40 participants from universities, governmental agencies, a patient self-help organization, and the pharmaceutical industry considered methodologic issues and research results relevant to determining the clinical importance of changes in the specific outcome measures previously recommended by IMMPACT for 4 core chronic pain outcome domains: (1) Pain intensity, assessed by a 0 to 10 numerical rating scale; (2) physical functioning, assessed by the Multidimensional Pain Inventory and Brief Pain Inventory interference scales; (3) emotional functioning,

assessed by the Beck Depression Inventory and Profile of Mood States; and (4) participant ratings of overall improvement, assessed by the Patient Global Impression of Change scale. It is recommended that 2 or more different methods be used to evaluate the clinical importance of improvement or worsening for chronic pain clinical trial outcome measures. Provisional benchmarks for identifying clinically important changes in specific outcome measures that can be used for outcome studies of treatments for chronic pain are proposed.

## Perspective

Systematically collecting and reporting the recommended information needed to evaluate the clinical importance of treatment outcomes of chronic pain clinical trials will allow additional validation of proposed benchmarks and provide more meaningful comparisons of chronic pain treatments.



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## Key words

Chronic pain; randomized clinical trials; outcome measures; clinical importance; assessment; quality of life; physical functioning; emotional functioning; global ratings

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