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Title: 6-minute walk test (6MWT) in patients with idiopathic pulmonary fibrosis (IPF): Confirmation of the minimal clinically important difference (MCID)

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Body: Introduction: The 6MWT is a practical measure of exercise tolerance in patients with IPF. MCID estimates for 6MWT distance (6MWD) in patients with IPF have ranged between 10–58 m [1-3]; we sought to confirm these estimates in an independent cohort of patients with IPF. Methods: All patients randomized to placebo in the CAPACITY studies were included in the analysis. Both distribution- and anchor-based methods were used to estimate the MCID for 6MWD. Distribution-based analyses included standard error of measurement (SEM) and effect size (ES); anchor-based analyses used criterion referencing to estimate the difference in 6MWD between those who did and did not experience significant health events. Results: A total of 345 patients were included in the analysis. The mean (SD) baseline 6MWD was 404.6 m (90.4). The estimated SEM for 6MWD was 37 m (95% CI, 34–40). The estimated ES was 0.32, based on a mean change of 29.2 m from baseline to Wk 48. 6MWD values were significantly different for those who experienced the composite endpoint of hospitalization or death vs. those who did not; the corresponding MCID was 21.7 m (p=0.047). Conclusions: Analysis of 6MWD data from a large cohort of IPF patients yielded an MCID estimate of 22–37 m. This finding is consistent with previous estimates which, taken together, provide a meaningful benchmark for assessing 6MWD in patients with IPF.