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Contributions: GC, PDL, MGV and AB designed and planned the study. VC, PDL, GC and MGV wrote the report. PDL oversaw data pooling, data checking, reporting, and analyses. MGV was the study statistician. VS, AC, VG, VL, GMF, KB, RP, JS, GE, MA, MS, AB coordinated the clinical study in their own countries. GC coordinated the laboratories; GC, JA, SR, JH, HOM, HC, VvdV, JZ, UzS were responsible for the laboratory data in their group. All authors have revised and approved the final version of the report.