Response to: 'Riociguat in systemic sclerosis: a potential for disease modification' by Jain and Dhir

We thank Drs Jain and Dhir for their comments[1] regarding our recent article in *Annals of the Rheumatic Diseases* entitled 'Riociguat in patients with early diffuse cutaneous systemic sclerosis (RISE-SSc): randomised, double-blind, placebo-controlled multicentre trial'.[2] We agree that forced vital capacity (FVC) in millilitres, as in the Safety and Efficacy of Nintedanib in Systemic Sclerosis (SENSCIS) trial,[3] may be informative, and that the effects of riociguat on swollen and tender joints are also of interest.

We present below (table 1) the results from RIociguat Safety and Efficacy in patients with diffuse cutaneous Systemic Sclerosis (RISE-SSc) for FVC in millilitres for the overall population and for patients with interstitial lung disease (ILD) at baseline according to medical history. The results are broadly consistent with those reported for FVC%.[2] In view of the small sample sizes, a statistical analysis was not performed for the ILD subgroup. Data for total swollen joint scores and total tender joint scores are also shown. As the primary endpoint was not met, these data are purely descriptive and differences between the study arms cannot be considered statistically significant.

Data on tenosynovitis were not captured, and radiography was not routinely performed in the RISE-SSc study. Data on biomarkers including high-sensitivity C-reactive protein will be published as a separate paper.

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Table 1 FVC (mL) and total swollen and tender joint scores in the RISE-SSc study

	Riociguat	Placebo
FVC, mL, overall population		
Baseline	3068 (954) (n=60)	3294 (909) (n=61)
Week 52	2954 (881) (n=55)	3211 (850) (n=51)
Change from baseline at Week 52	−119 (242) (n=55)	−116 (309) (n=51)
FVC, mL, patients with ILD by medical history		
Baseline	2690 (768) (n=12)	3083 (1221) (n=13)
Week 52	2616 (799) (n=11)	2843 (1168) (n=11)
Change from baseline at Week 52	−95 (113) (n=11)	−244 (347) (n=11)
Total swollen joint score (overall population)		
Baseline	2.95 (6.07) (n=60)	1.07 (2.55) (n=61)
Week 52	2.29 (5.11) (n=59)	1.14 (3.26) (n=59)
Total tender joint score (overall population)		
Baseline	3.90 (7.25) (n=60)	2.10 (4.78) (n=61)
Week 52	3.73 (7.09) (n=59)	2.34 (6.08) (n=59)

Values are mean (SD).
FVC, forced vital capacity; ILD, interstitial lung disease; RISE-SSc, RIociguat Safety and Efficacy in patients with diffuse cutaneous Systemic Sclerosis; SD, standard deviation.

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Competing interests DK reports grant support from NIH, Immune Tolerance Network, Bayer AG, Bristol-Myers Squibb, Horizon, Pfizer; consultancy with Acceleron, Actelion, AbbVie, Amgen, Bayer AG, Boehringer Ingelheim, CSL Behring, Corbus, Galapagos, Genentech/Roche, GlaxoSmithKline, Horizon, Merck, Mitsubishi Tanabe Pharma, Sanofi-Aventis, and United Therapeutics; and ownership of stocks in Eicos Sciences, Inc. OD reports consultancy relationship and/or has received research funding from AbbVie, Actelion, Acceleron Pharma, Amgen, AnaMar, Baecon Discovery, Blade Therapeutics, Bayer AG, Boehringer Ingelheim, Catenion, Competitive Corpus, Drug Development International Ltd, CSL Behring, ChemomAb, Ergonex, Galapagos NV, Glenmark Pharmaceuticals, GlaxoSmithKline, Horizon (Curzion) Pharmaceuticals, Inventiva, Italfarmaco, iQone, iQvia, Kymera Therapeutics, Lilly, medac, Medscape, Mitsubishi Tanabe Pharma, MSD, Novartis, Pfizer, Roche, Sanofi, Target Bio Science and UCB in the area of potential treatments of scleroderma and its complications. In addition, he has a patent mir-29 for the treatment of systemic sclerosis issued (US8247389, EP2331143)

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