

Efficacy of nintedanib in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD) and internal organ involvement: data from the SENSIS trial

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INTRODUCTION

- SSc is a heterogeneous autoimmune disease that may affect several organs. Organ involvement typically develops in the early years of the disease.^{1,2}
- In the SENSIS trial in patients with SSc-ILD, nintedanib reduced the rate of decline in forced vital capacity (FVC) (mL/year) over 52 weeks by 44% versus placebo.³

AIM

- To assess the extent of internal organ involvement related to SSc at baseline and the effect of nintedanib on the rate of FVC decline in subgroups by organ involvement in the SENSIS trial.

METHODS

Trial design

- Patients in the SENSIS trial had SSc with first non-Raynaud symptom within ≤ 7 years before screening, extent of fibrotic ILD $\geq 10\%$ on HRCT, FVC $\geq 40\%$ predicted, and DLco 30–89% predicted. Patients with clinically significant pulmonary hypertension were excluded.
- Patients taking prednisone ≤ 10 mg/day and/or stable therapy with mycophenolate or methotrexate for ≥ 6 months prior to randomisation were allowed to participate.
- Patients were randomised to receive nintedanib or placebo.

Analyses

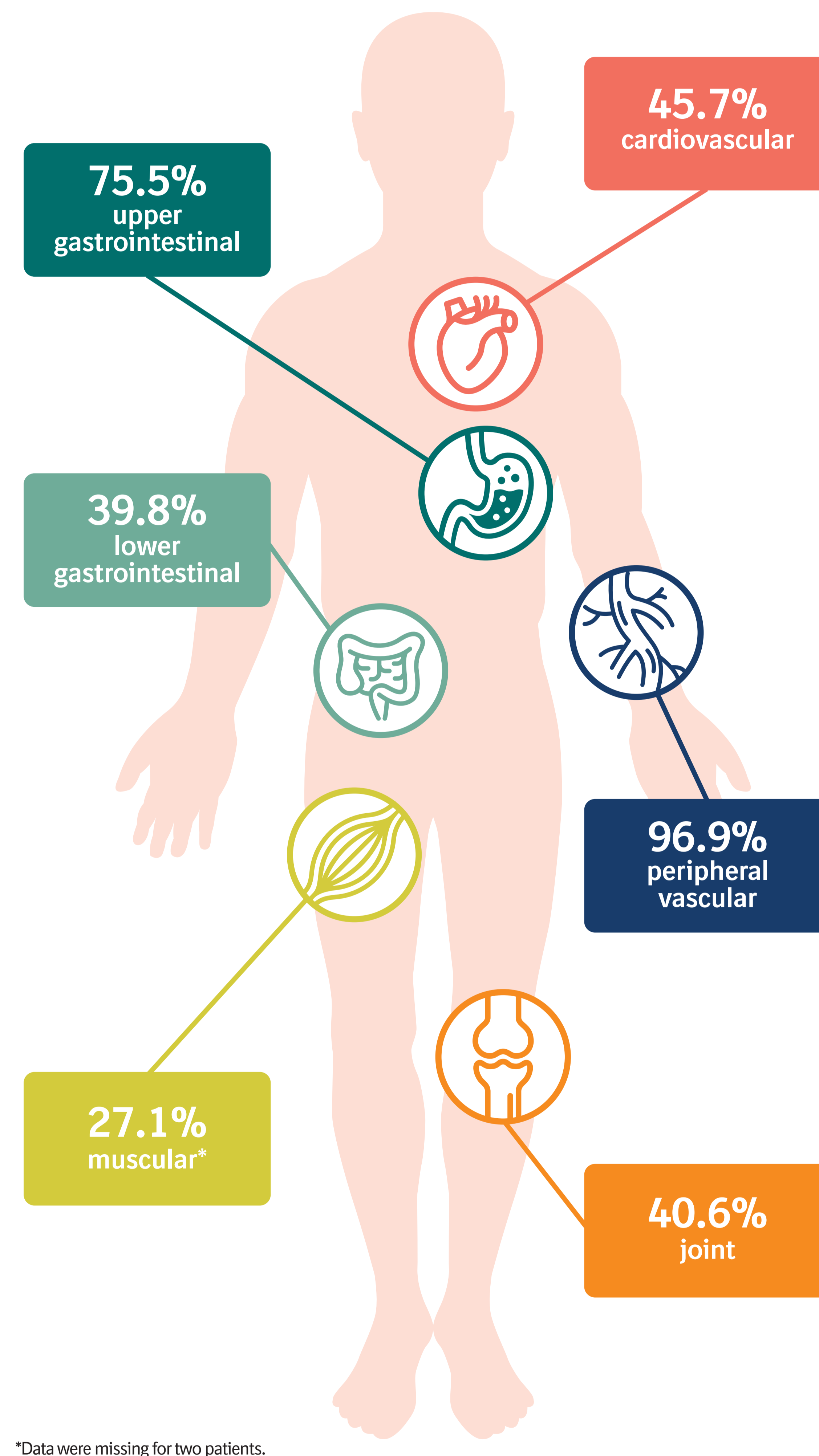
- In *post-hoc* analyses, we analysed the rate of decline in FVC (mL/year) over 52 weeks in subgroups with and without different types of SSc-related internal organ involvement: upper gastrointestinal; lower gastrointestinal; cardiovascular; peripheral vascular; muscular; joint. These subgroups were defined based on patients' SSc-related medical history as reported in the case report form.
- Interaction p-values were calculated to assess potential heterogeneity in the treatment effect of nintedanib between the subgroups. A random coefficient regression model with fixed effects of anti-topoisomerase I antibody status, sex, baseline FVC, age and height and including baseline-by-time, treatment-by-subgroup and treatment-by-subgroup-by-time interaction terms was used.

CONCLUSIONS

- Patients with SSc-ILD in the SENSIS trial had diverse complications related to SSc.
- There was no evidence of a differential treatment effect of nintedanib on reducing the rate of decline in FVC based on gastrointestinal, cardiovascular, joint, or muscular involvement at baseline.

RESULTS

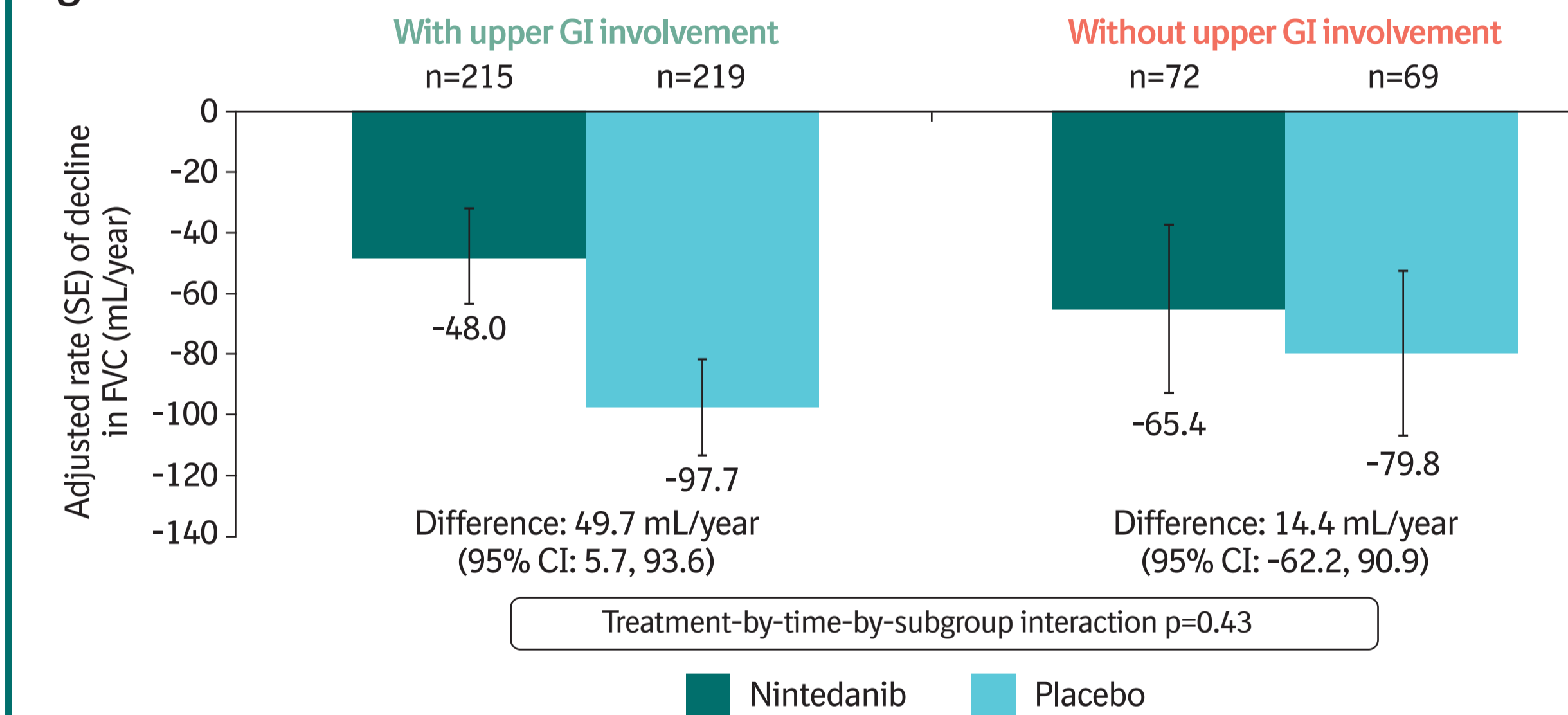
Organ involvement at baseline (n=576)



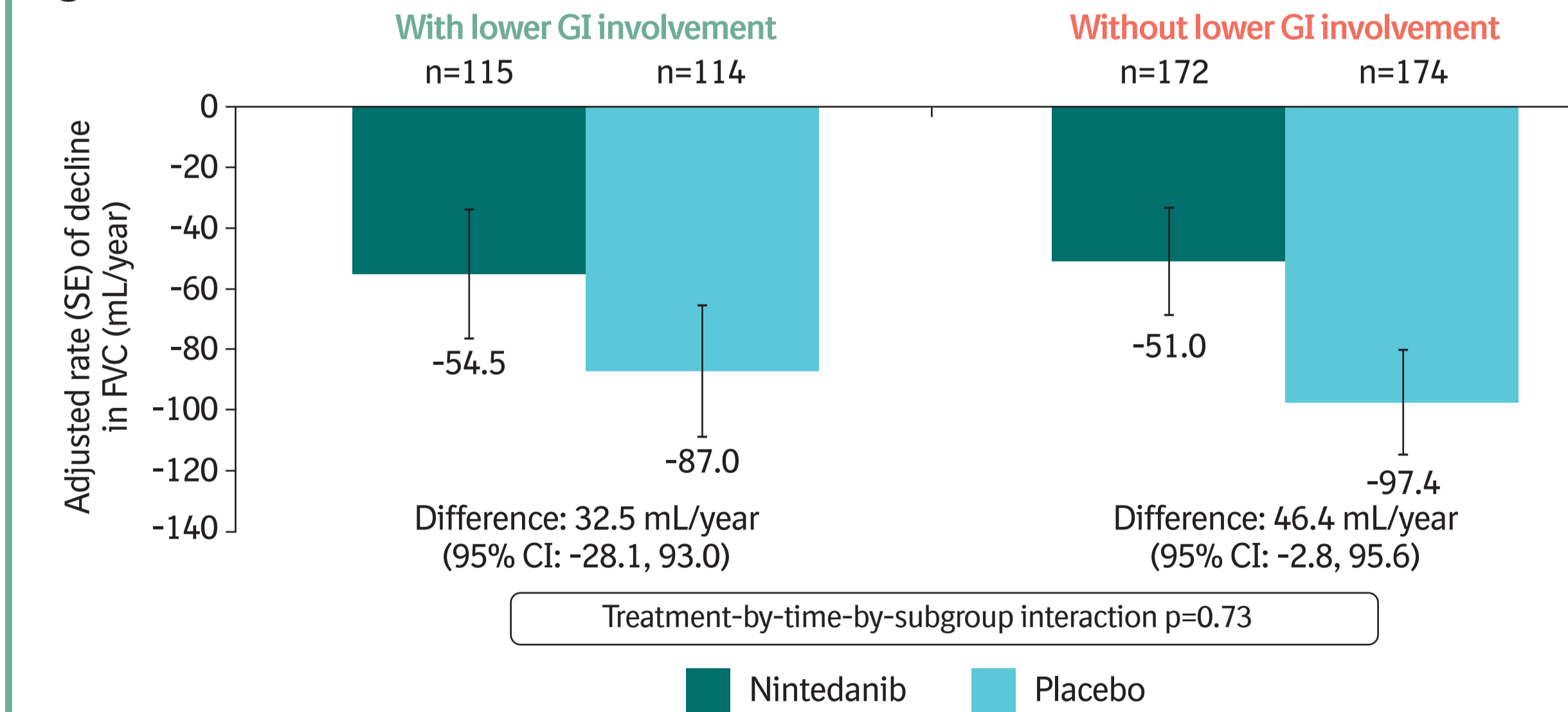
Summary of subgroup analyses of rate of decline in FVC over 52 weeks

- In the placebo group, the rate of decline in FVC was numerically greater in patients with upper gastrointestinal involvement and in patients without joint involvement or muscular involvement.
- The exploratory interaction p-values did not indicate heterogeneity in the effect of nintedanib versus placebo on reducing the rate of decline in FVC between the subgroups based on organ involvement.
- The number of patients with no peripheral vascular involvement (n=18) was too small for the results to be interpreted.

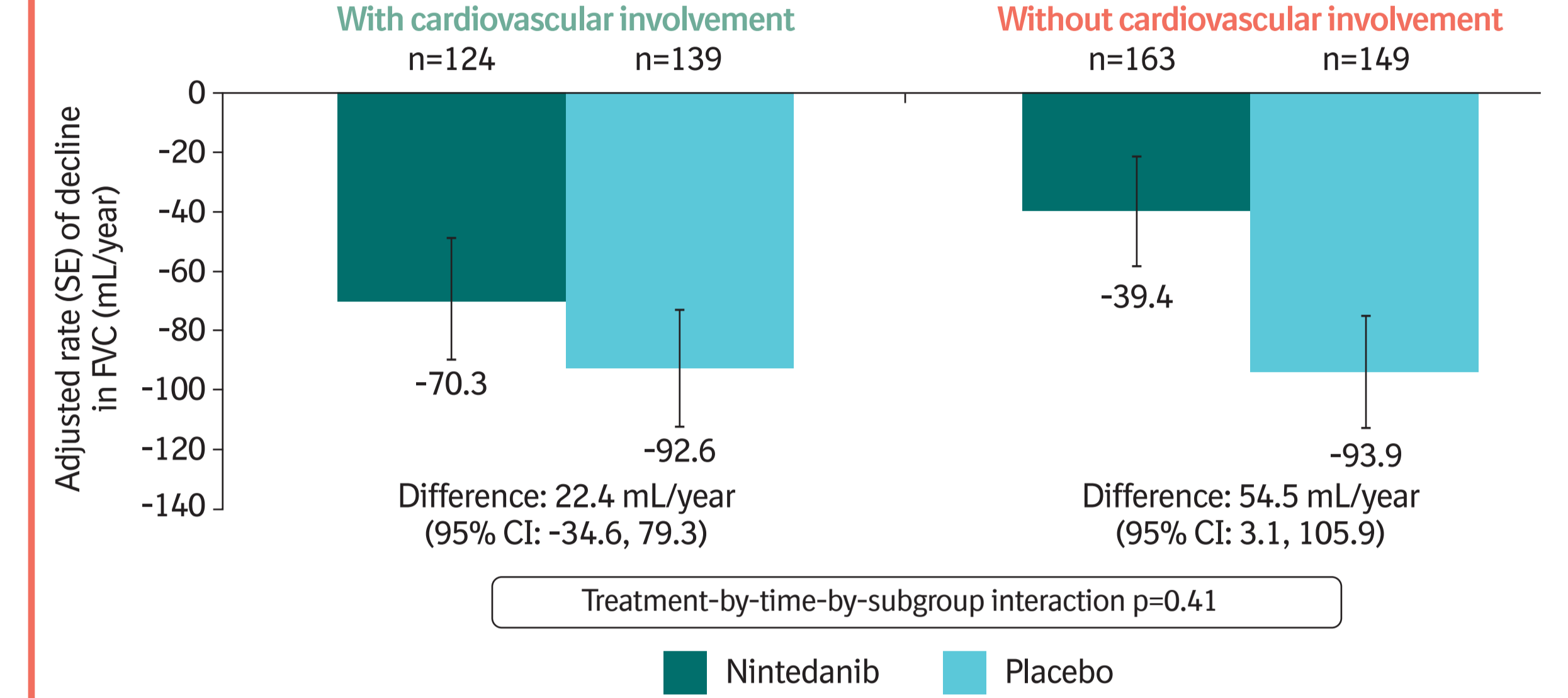
Rate of decline in FVC (mL/year) over 52 weeks in subgroups by upper gastrointestinal involvement



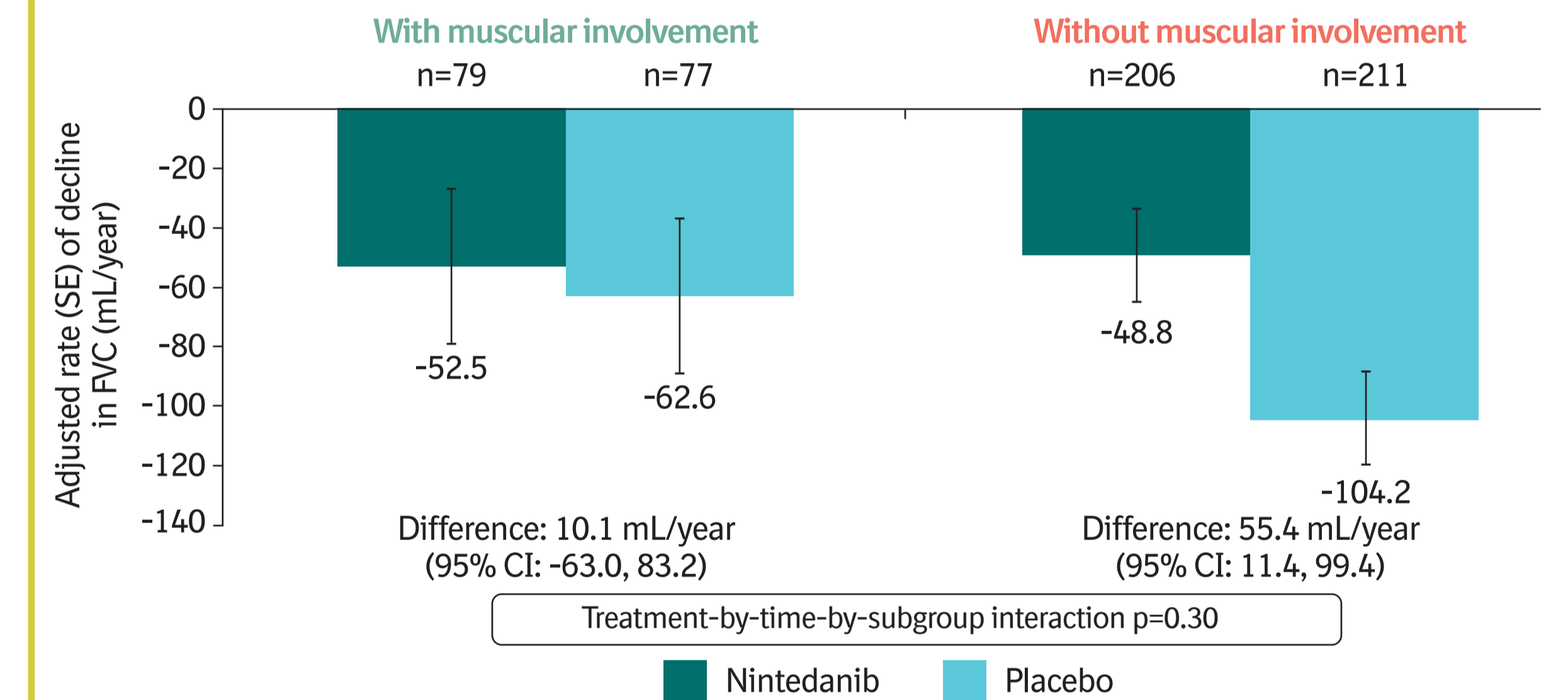
Rate of decline in FVC (mL/year) over 52 weeks in subgroups by lower gastrointestinal involvement



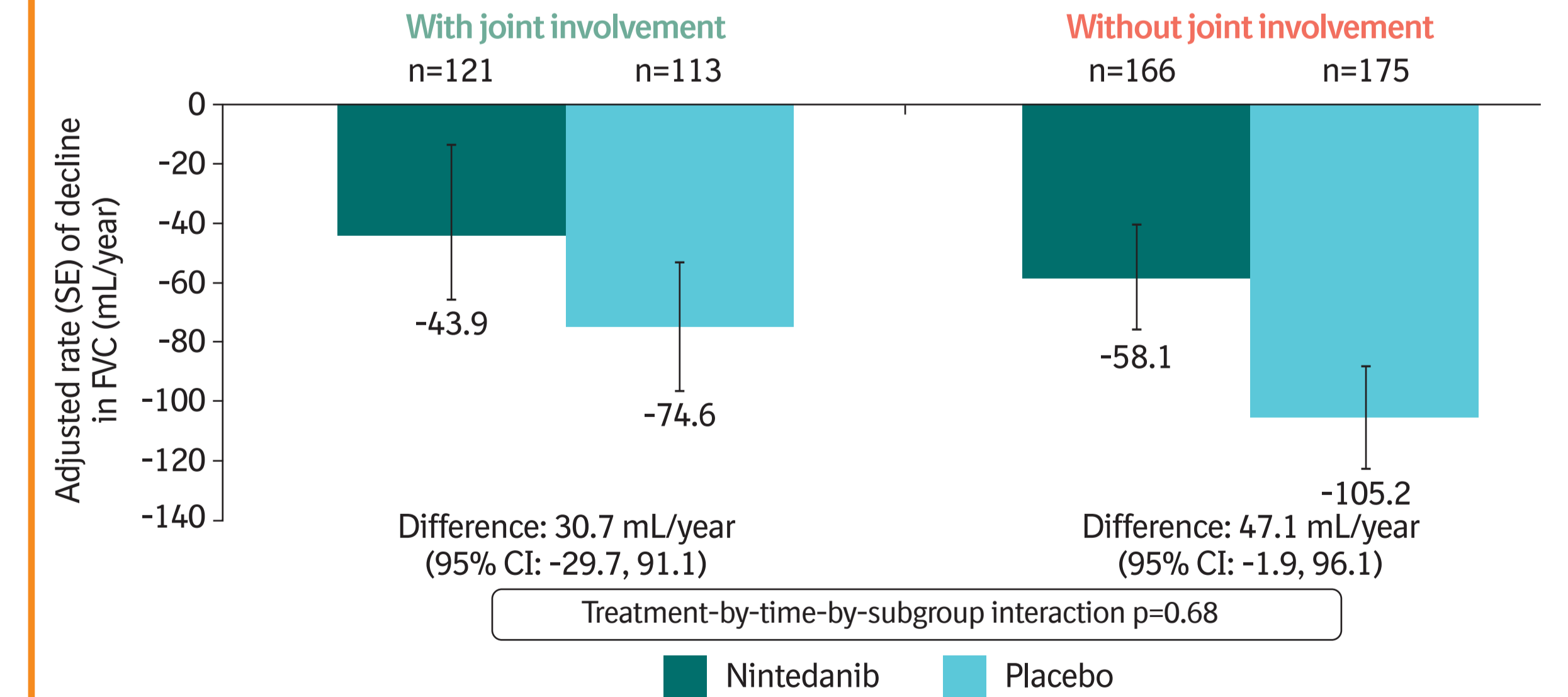
Rate of decline in FVC (mL/year) over 52 weeks in subgroups by cardiovascular involvement



Rate of decline in FVC (mL/year) over 52 weeks in subgroups by muscular involvement



Rate of decline in FVC (mL/year) over 52 weeks in subgroups by joint involvement



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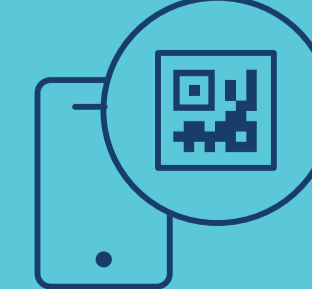
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