

# Disease progression events in trials of nintedanib in patients with idiopathic pulmonary fibrosis

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## INTRODUCTION

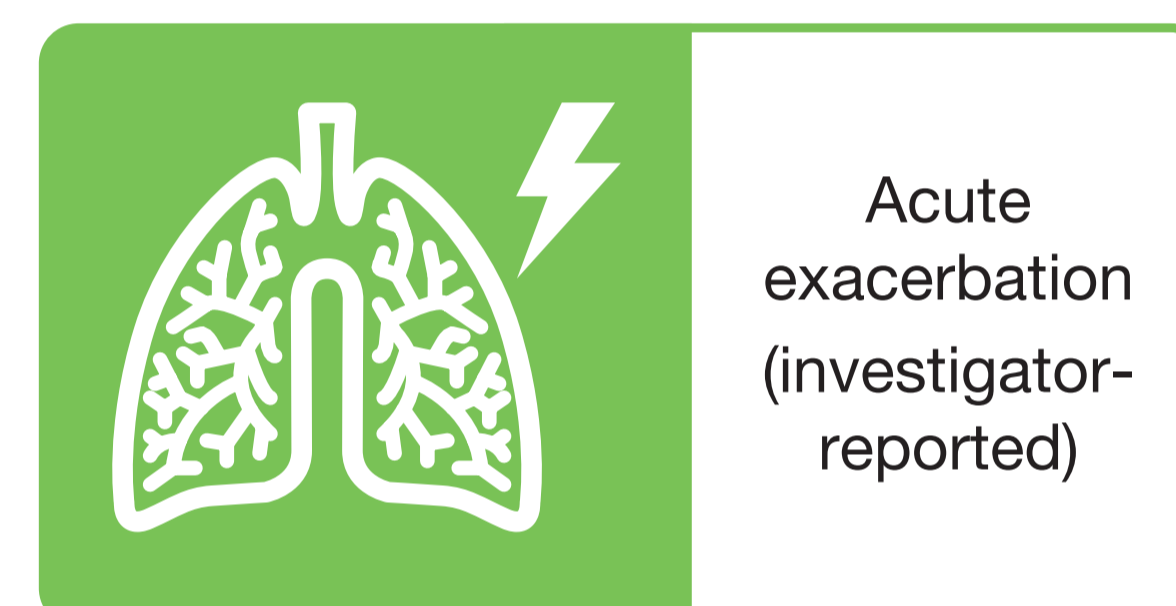
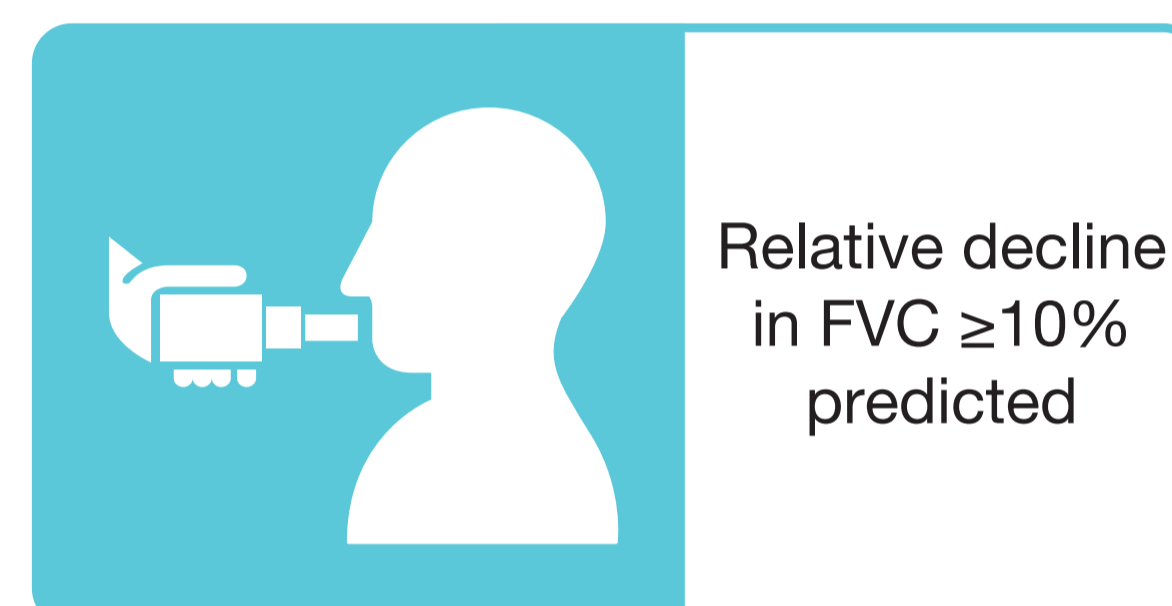
- Idiopathic pulmonary fibrosis (IPF) is a progressive fibrosing interstitial lung disease characterized by decline in lung function and high mortality.<sup>1</sup>
- Acute exacerbations and hospitalizations are common features of the clinical course of IPF.<sup>2,3</sup>

## AIM

- To assess events reflecting disease progression in patients with IPF treated with nintedanib versus placebo.

## METHODS

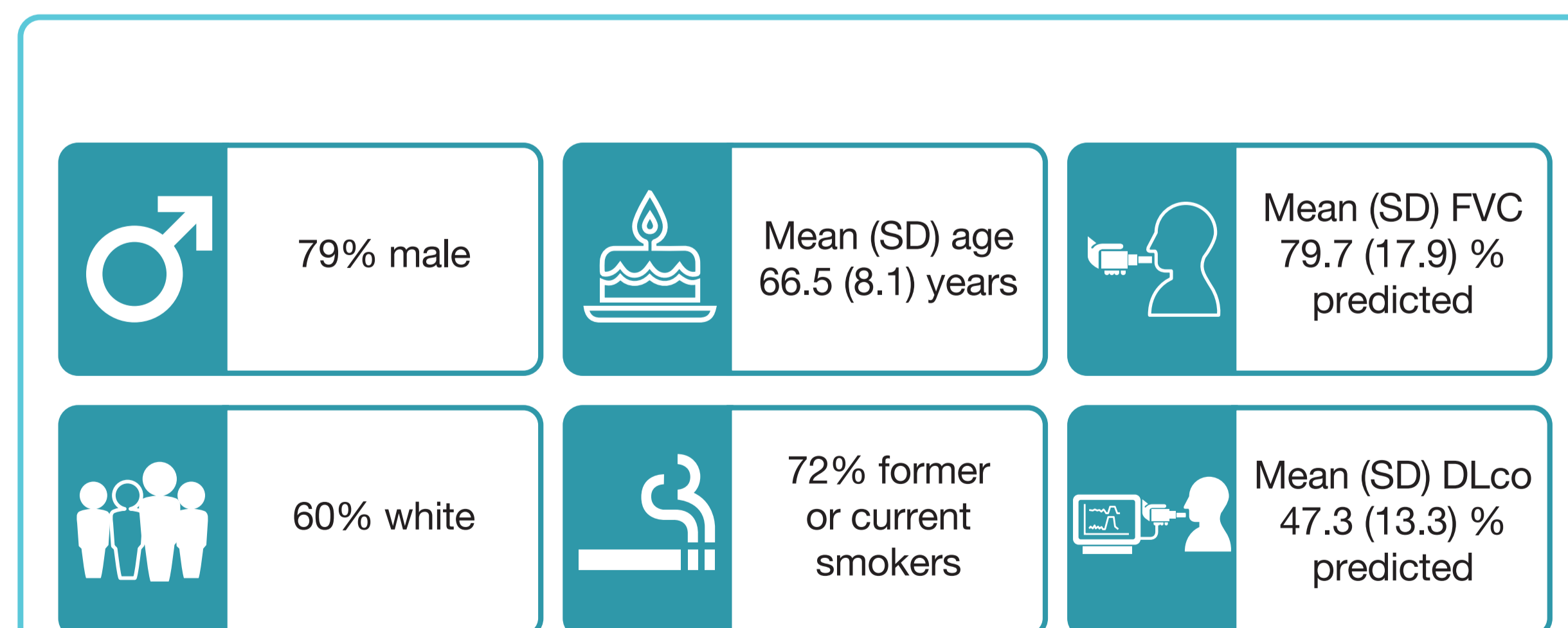
- Data were pooled from the TOMORROW trial<sup>4</sup> and two INPULSIS trials<sup>5</sup> in which subjects were randomized to receive nintedanib or placebo.
- The occurrence of progression events over the 52-week treatment period plus 7 days was analyzed post-hoc.
- Progression events were defined as:



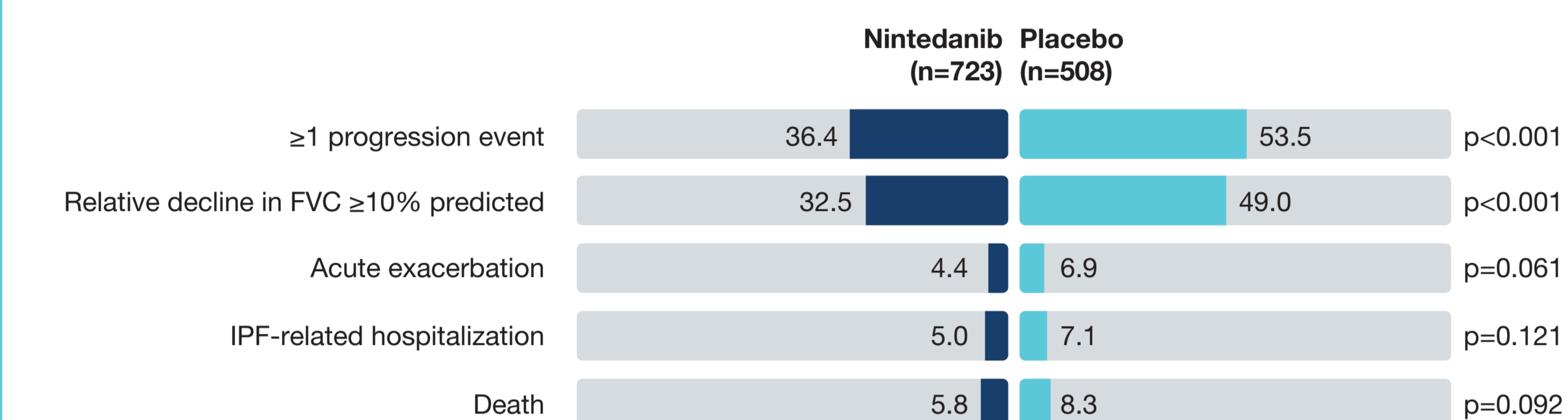
- Events of the same type on different dates were counted as separate events. Different types of event on the same date were counted as one event

## RESULTS

### Baseline characteristics

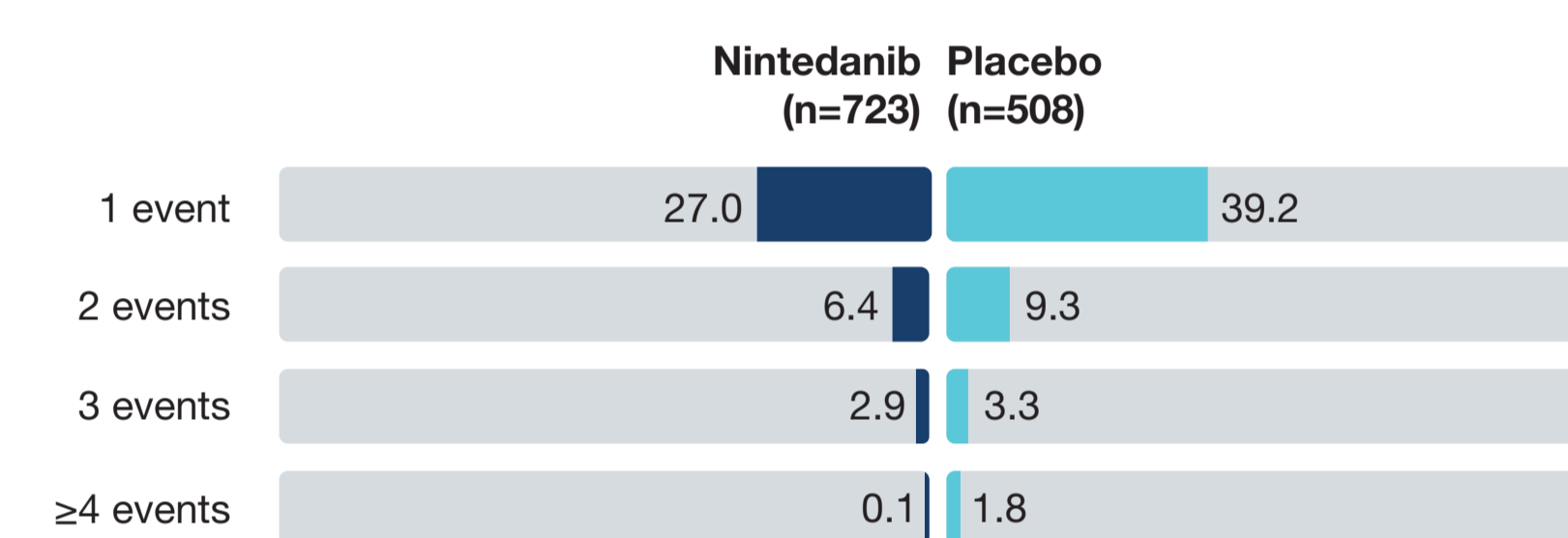


### Progression events



Data are % of patients. Chi-squared test was used to calculate p-values.

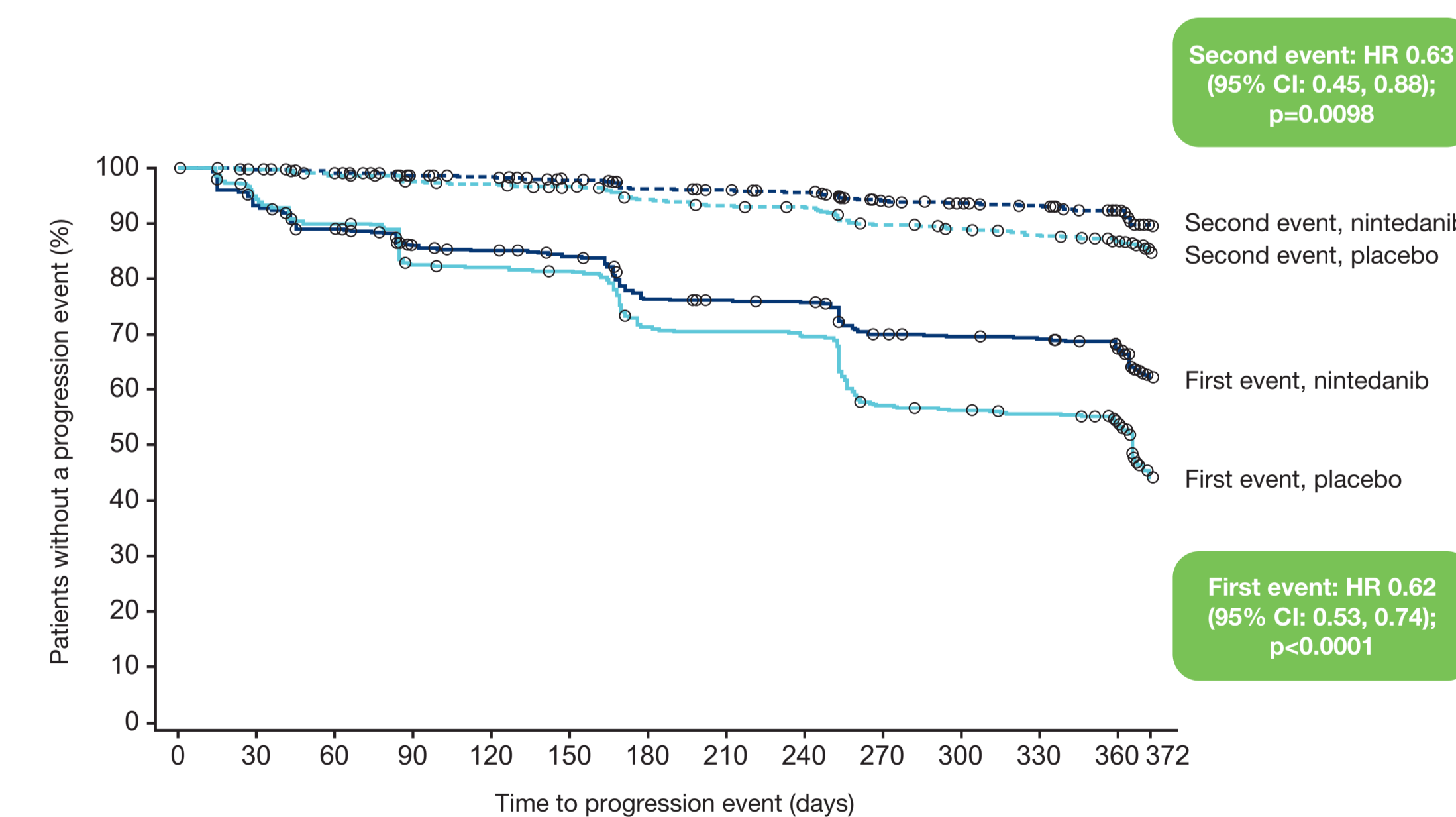
### Number of progression events



Data are % of patients.

### Time to first and second progression events

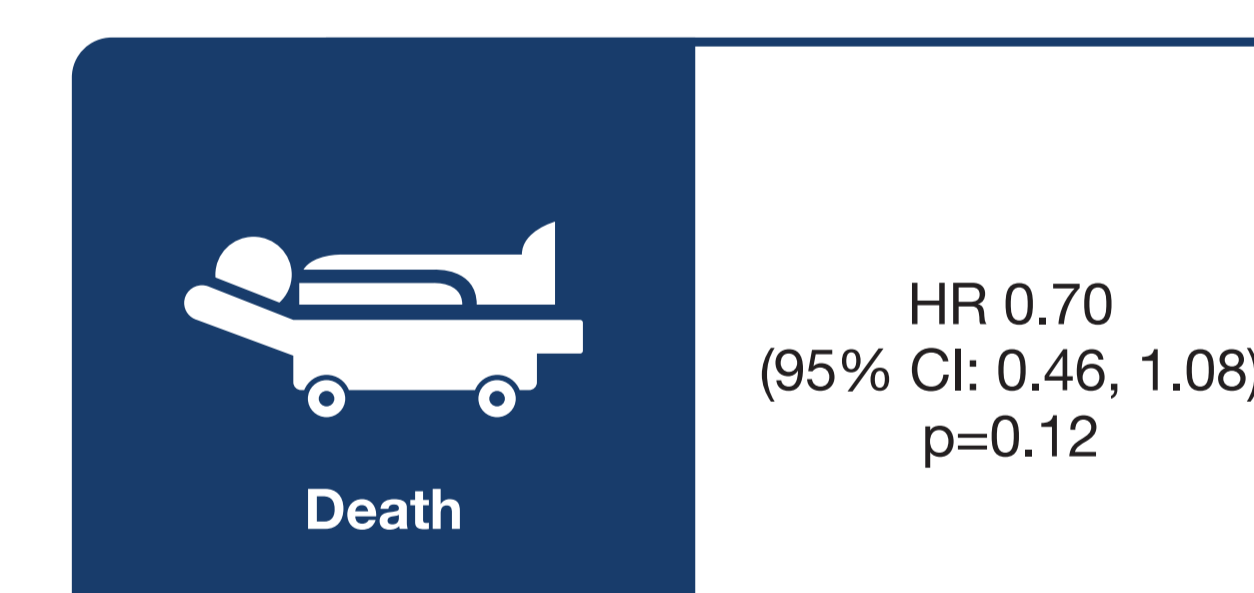
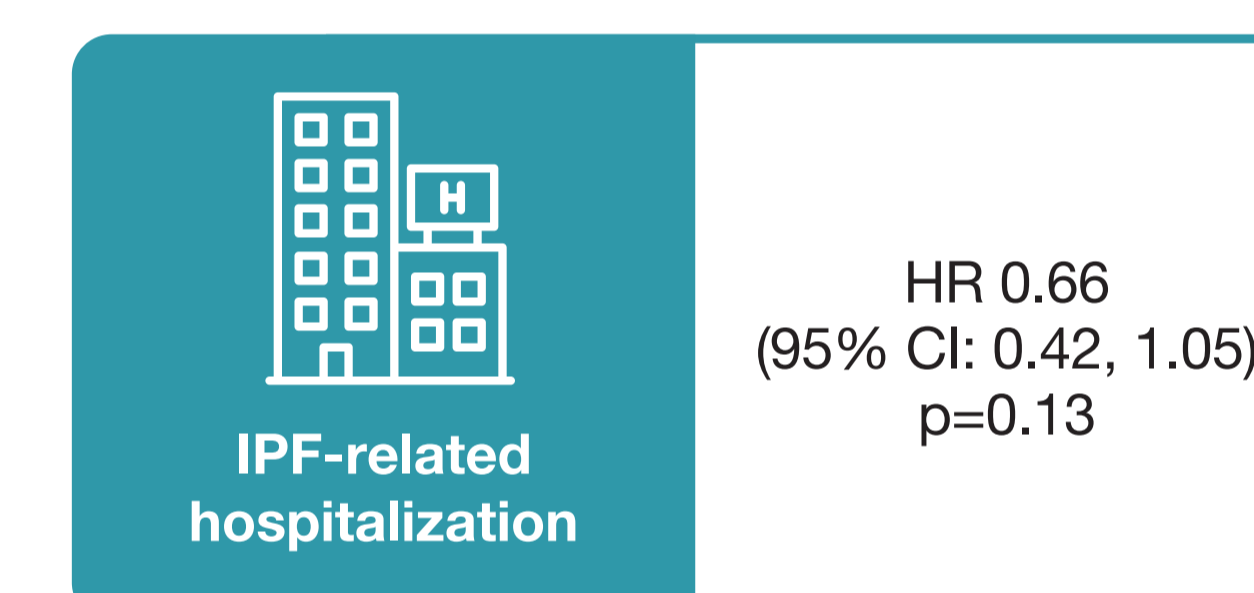
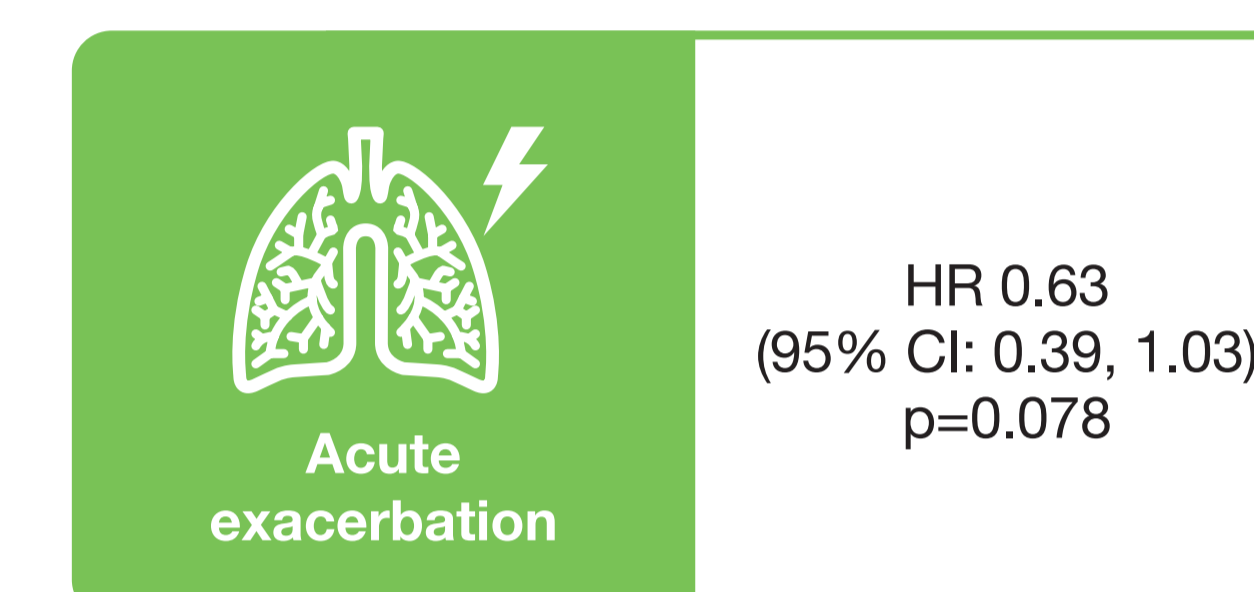
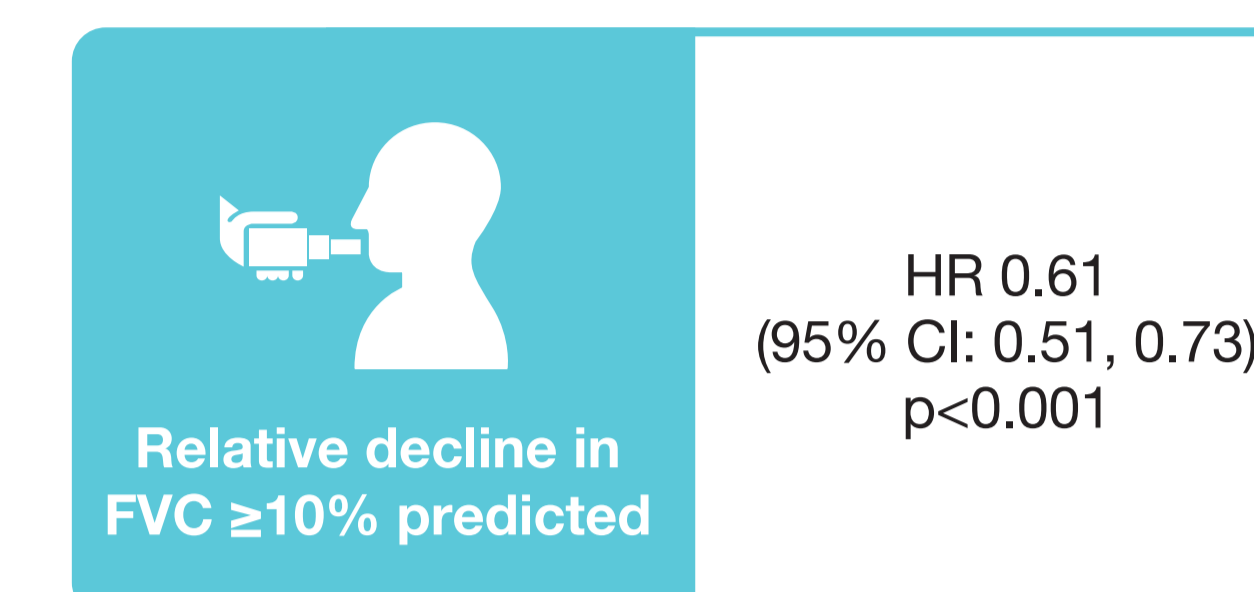
- Nintedanib significantly reduced the risk of a first and second progression event compared with placebo.



Number at risk	0	30	60	90	120	150	180	210	240	270	300	330	360	372
First event, nintedanib	723	673	638	608	600	589	533	527	523	481	476	472	453	376
Second event, nintedanib	723	719	712	695	690	678	664	658	652	633	624	617	594	514
First event, placebo	508	480	453	413	410	406	355	350	346	284	278	273	258	184
Second event, placebo	508	505	496	486	483	477	462	456	452	435	428	421	404	346

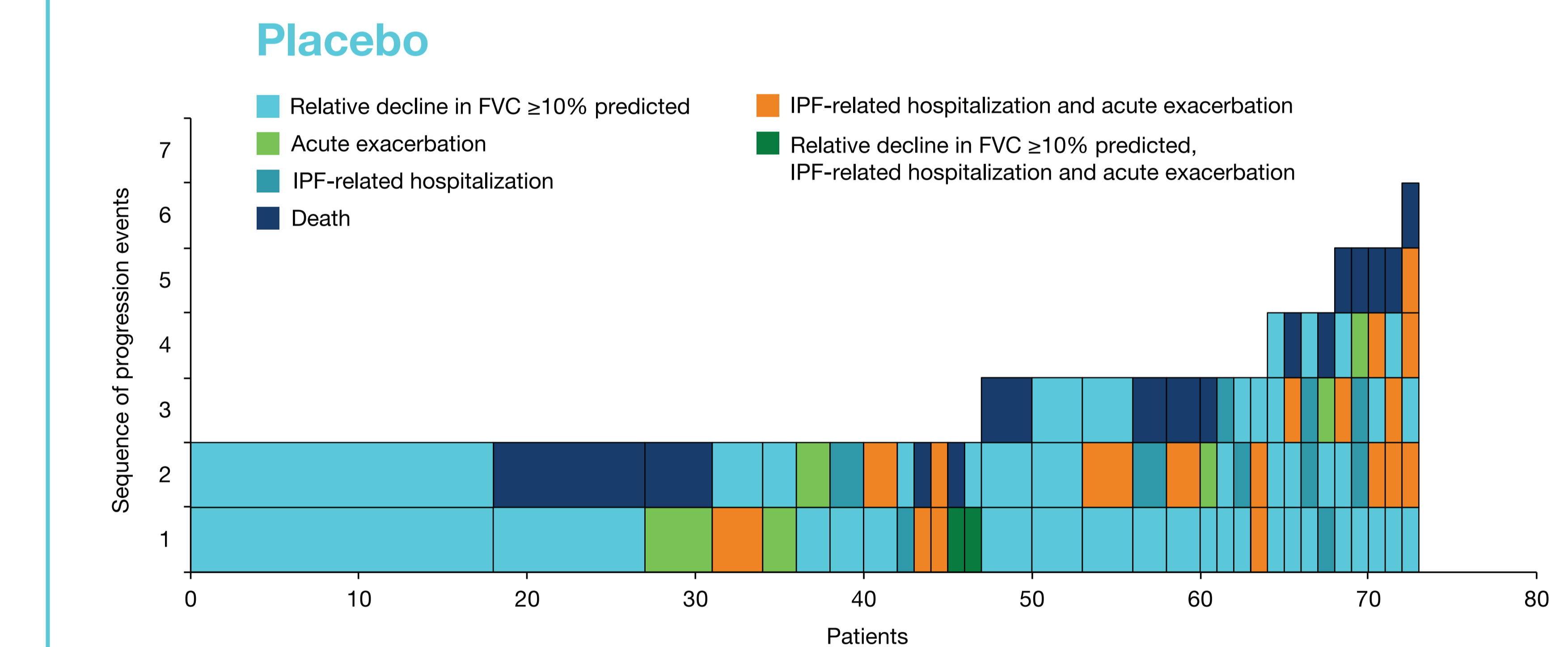
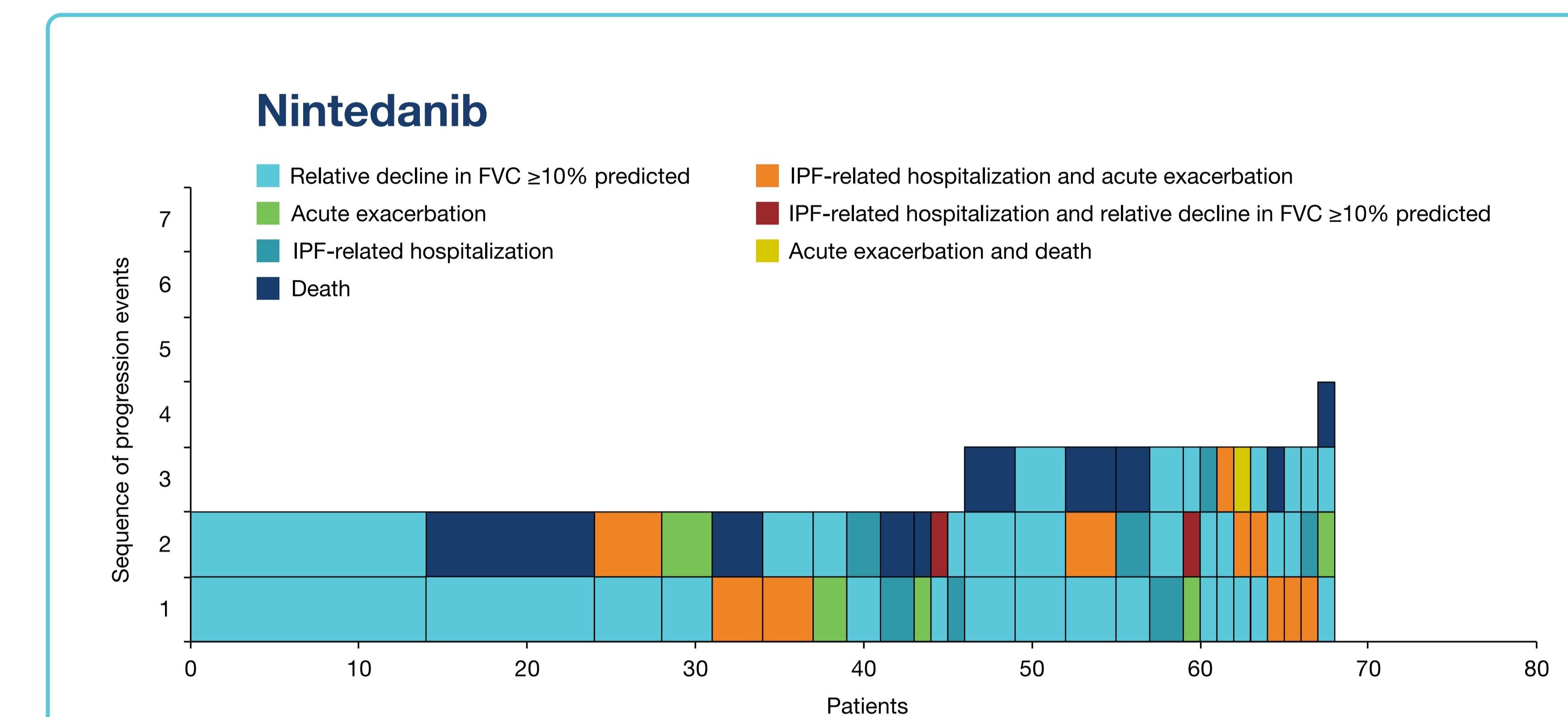
A log-rank test was used to compare treatment groups and a Cox model was used to determine hazard ratios.

### Time to first progression event by type of event



### Incidence and sequence of multiple disease progression events up to 52 weeks in patients who had >1 event

- The below figures show the number of patients with each sequence of progression events. The box at the bottom of the column represents the event that occurred first, the next box up the next event that occurred, and so on.



## CONCLUSIONS

- In randomized controlled trials, events reflecting disease progression occurred in smaller proportions of patients with IPF treated with nintedanib than placebo over 52 weeks.

## References

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