

The IFN β -1b 16-year Long-term Follow-up Study

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The Interferon beta-1b 16-year Long-term Follow-up Study: The Results

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Long-term Follow-up Study Group**

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First presentation of the final data

Citation: Ebers G, Rice G, Konieczny A, Traboulsee A, Langdon D, Kaskel PCV, Salazar-Gruesso E. The interferon beta-1b 16-year long-term follow-up study: the final results. Neurology 2006;66(Suppl 2):A32. Abstract.

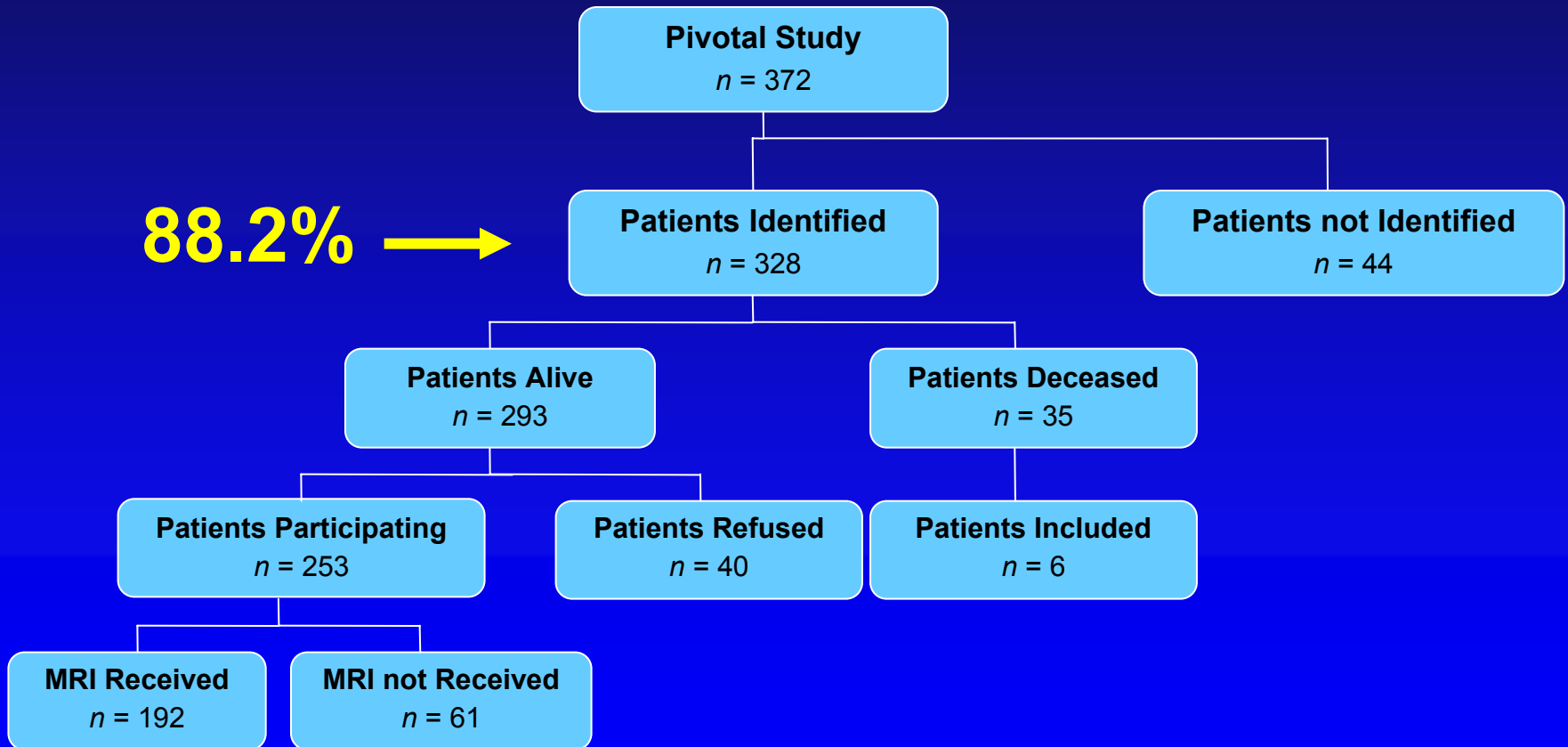
Rationale

- The pivotal North American Betaseron[®] study demonstrated the efficacy, safety and tolerability of Betaseron[®] in patients with relapsing-remitting (RRMS)
- Based on this trial, Betaseron[®] became the first approved immunomodulatory therapy in this indication
- Given that MS evolves over a period of several decades, there is a need for information on long-term treatment outcome. However, data on the long-term (>10 years) benefits of interferon-beta (IFNB) treatment are not currently available
- The 16-year long-term follow-up (LTF) evaluates the long-term safety and efficacy of Betaseron[®] in patients with RRMS who participated in the pivotal North American trial

Study Design

- The 16-year LTF study was a multicenter, observational study in patients with relapsing forms of MS who had participated in the North American Betaseron[®] pivotal study
- Cross-sectional data from patients who took part in the original pivotal trial were collected for comparison with well-characterized natural history data
- Analyses were exploratory and descriptive in nature and designed to evaluate the long-term treatment effects of Betaseron[®] on clinical and imaging parameters, cognitive function, and patient-reported outcomes
- Patients were stratified according to their original dose group (250 µg, 50 µg, or placebo) and by overall length of exposure to Betaseron[®] (<10%, 10–80%, or >80% of time since the start of the pivotal trial)

Patient Demographics

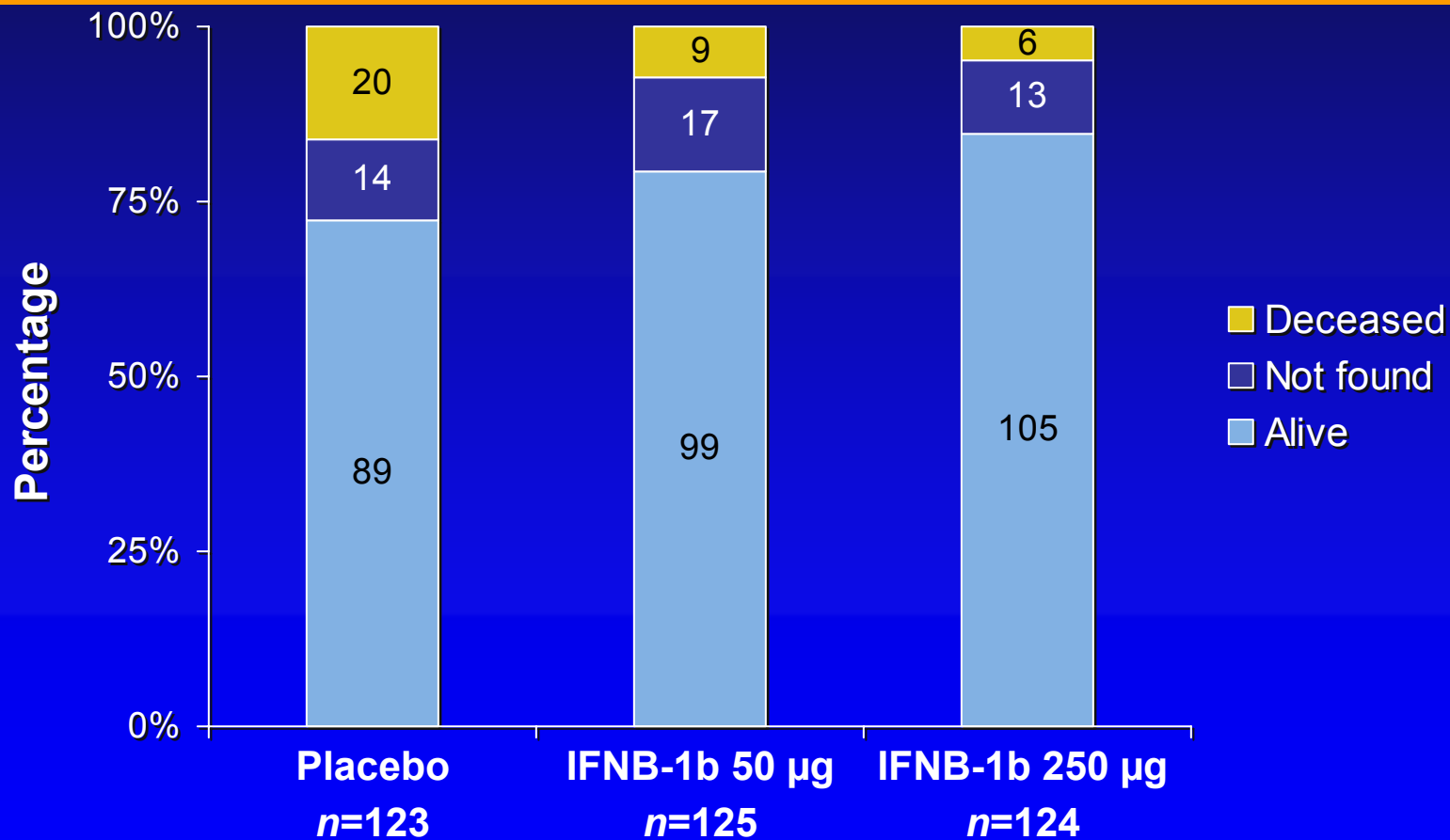


Patient Demographics

	IFNB-1b <10%	IFNB-1b 10–80%	IFNB-1b >80%
Patients (<i>n</i>)	48	154	49
Current age (years)			
Mean ± SD	51.3 ± 8.22	51.5 ± 7.34	51.0 ± 6.88
Gender (%)			
Male / Female	28.8 / 71.2	30.5 / 69.5	35.3 / 64.7
Time since MS diagnosis			
Mean ± SD	19.5 ± 3.66	20.5 ± 4.61	19.9 ± 4.01
Median	19.0	19.0	18.0
Annualized relapse rate (2 years prior to start of treatment) Mean ± SD	1.67 ± 0.63	1.67 ± 0.78	1.73 ± 0.86
Expanded Disability Status Scale (EDSS) at start of treatment (median)	3.0	3.0	2.5

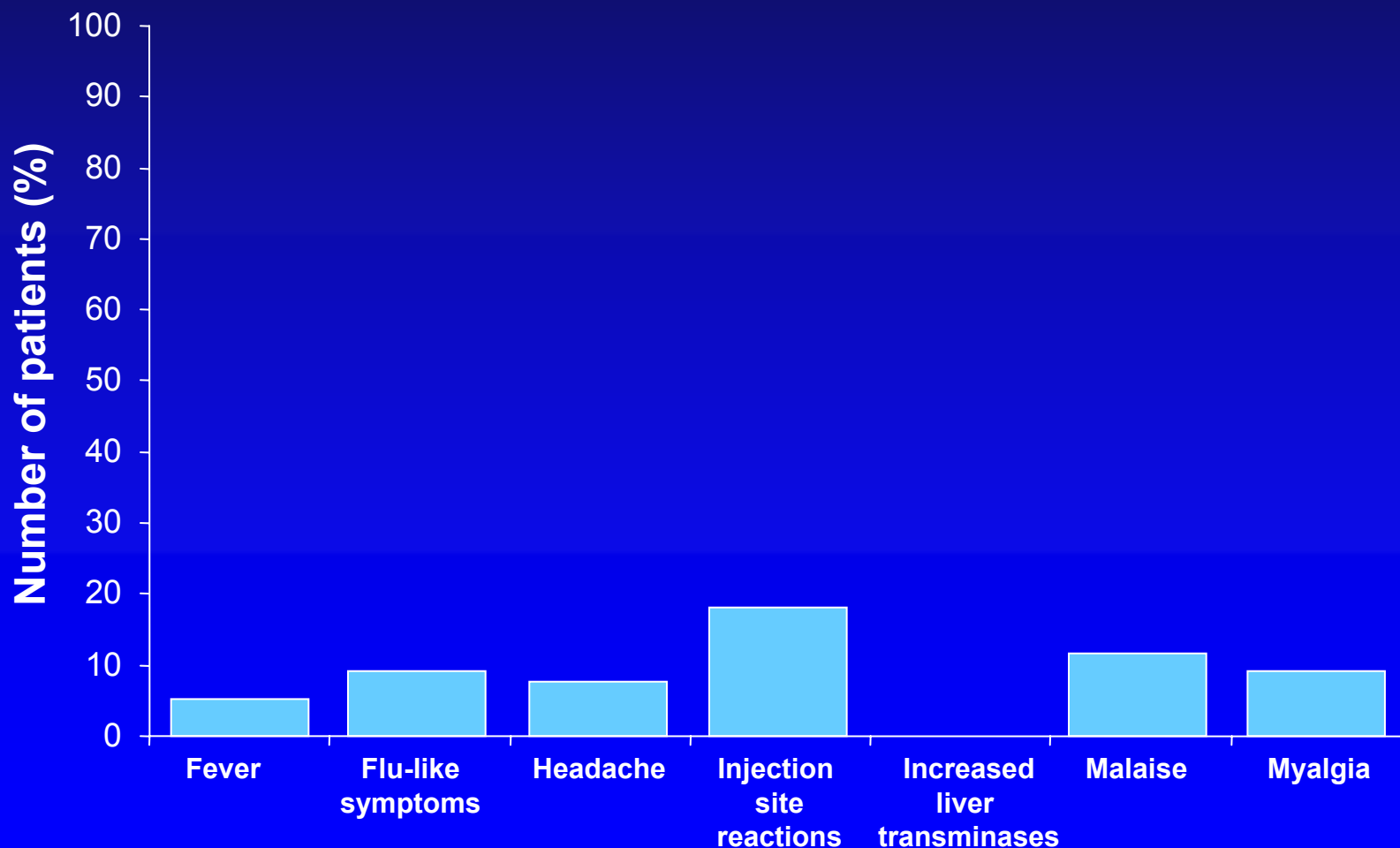
The baseline characteristics of the intent-to-treat population were equally balanced between groups and the LTF patients are representative of the original trial population

Patient Disposition in the Intent-to-treat Population



Numbers within columns indicate the actual number of patients affected

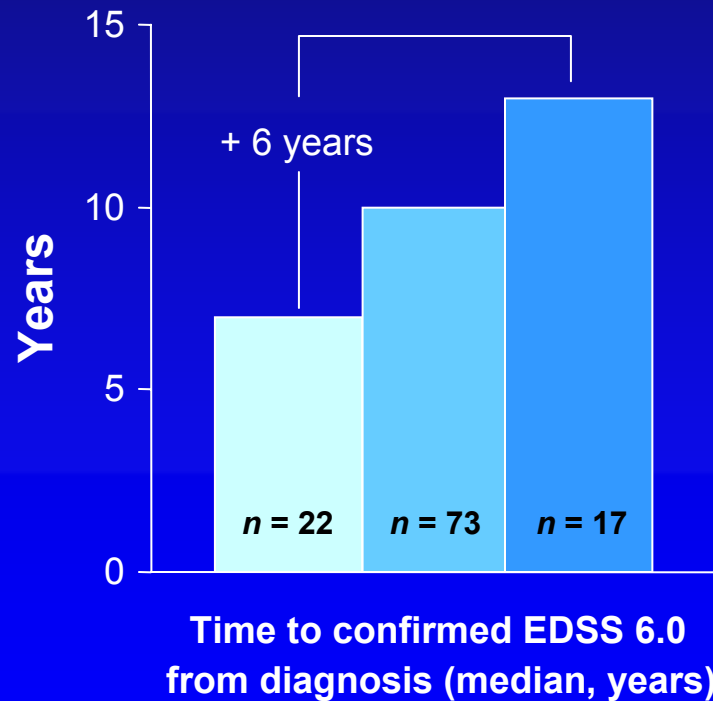
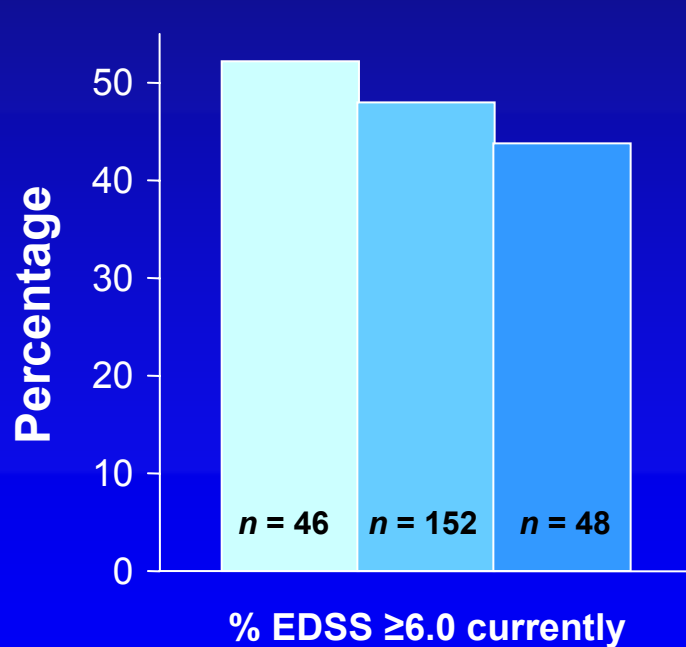
Very Low Rate of Adverse Events Reported During the Last 6 Months in Patients on Betaseron® Treatment for the Last 2 Years*



*not adjusted for drop-outs in the last 2 years

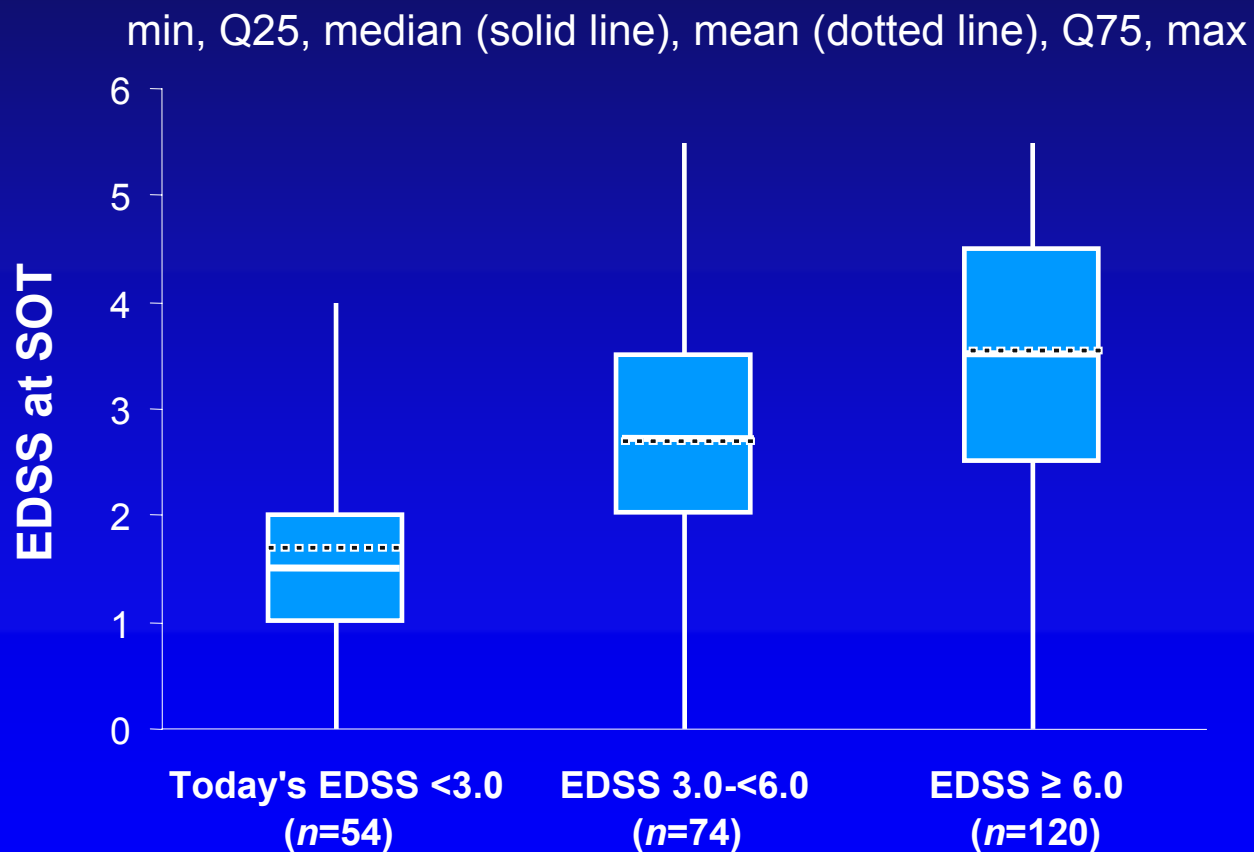
Patients Reaching EDSS 6.0 and Median Time to EDSS 6.0 According to Exposure to Betaseron®

■ IFNB-1b <10% ■ IFNB-1b 10-80% ■ IFNB-1b >80%



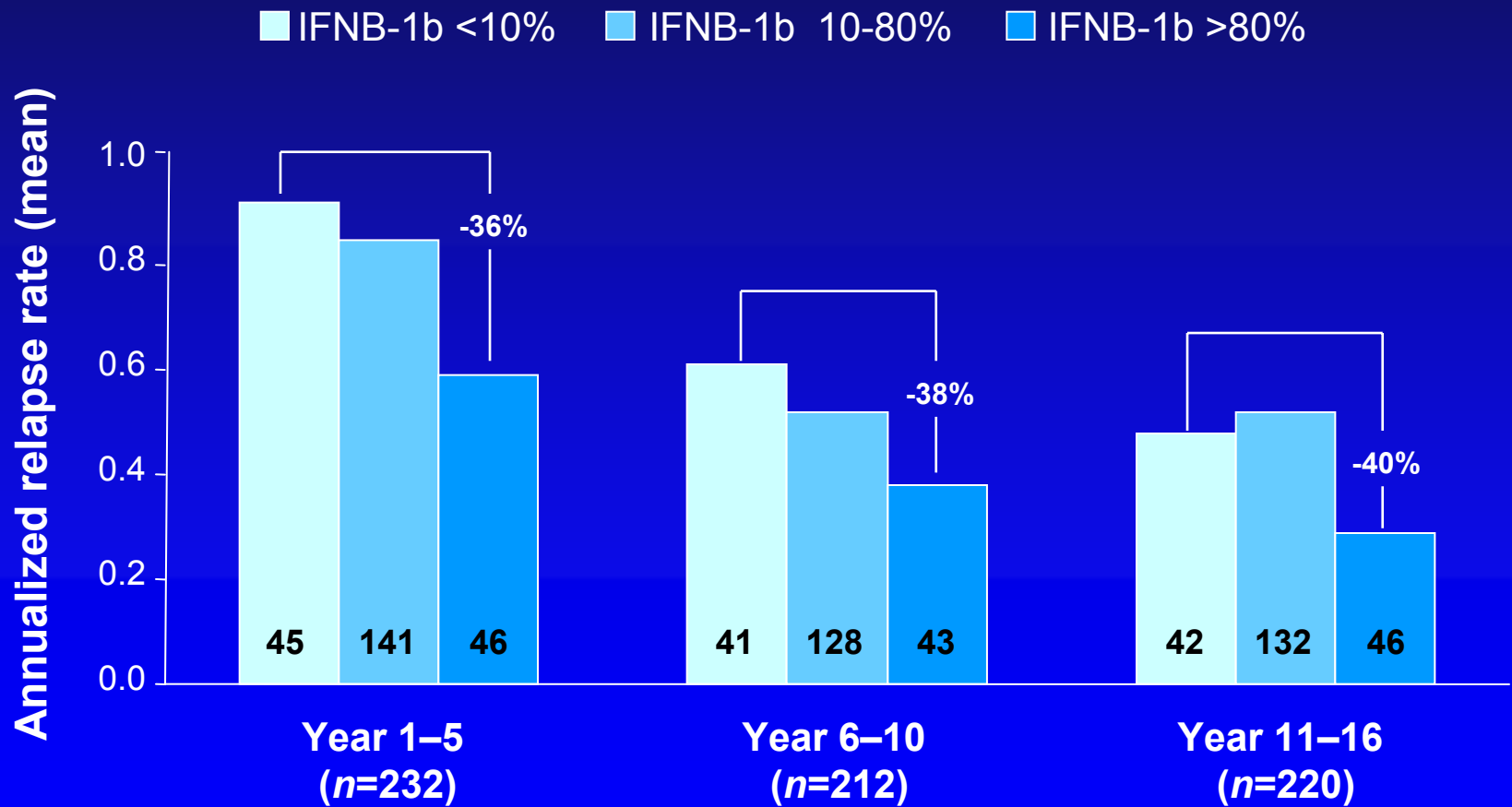
Not including deceased patients

Current EDSS Scores Compared to That at Start of Treatment (SOT)

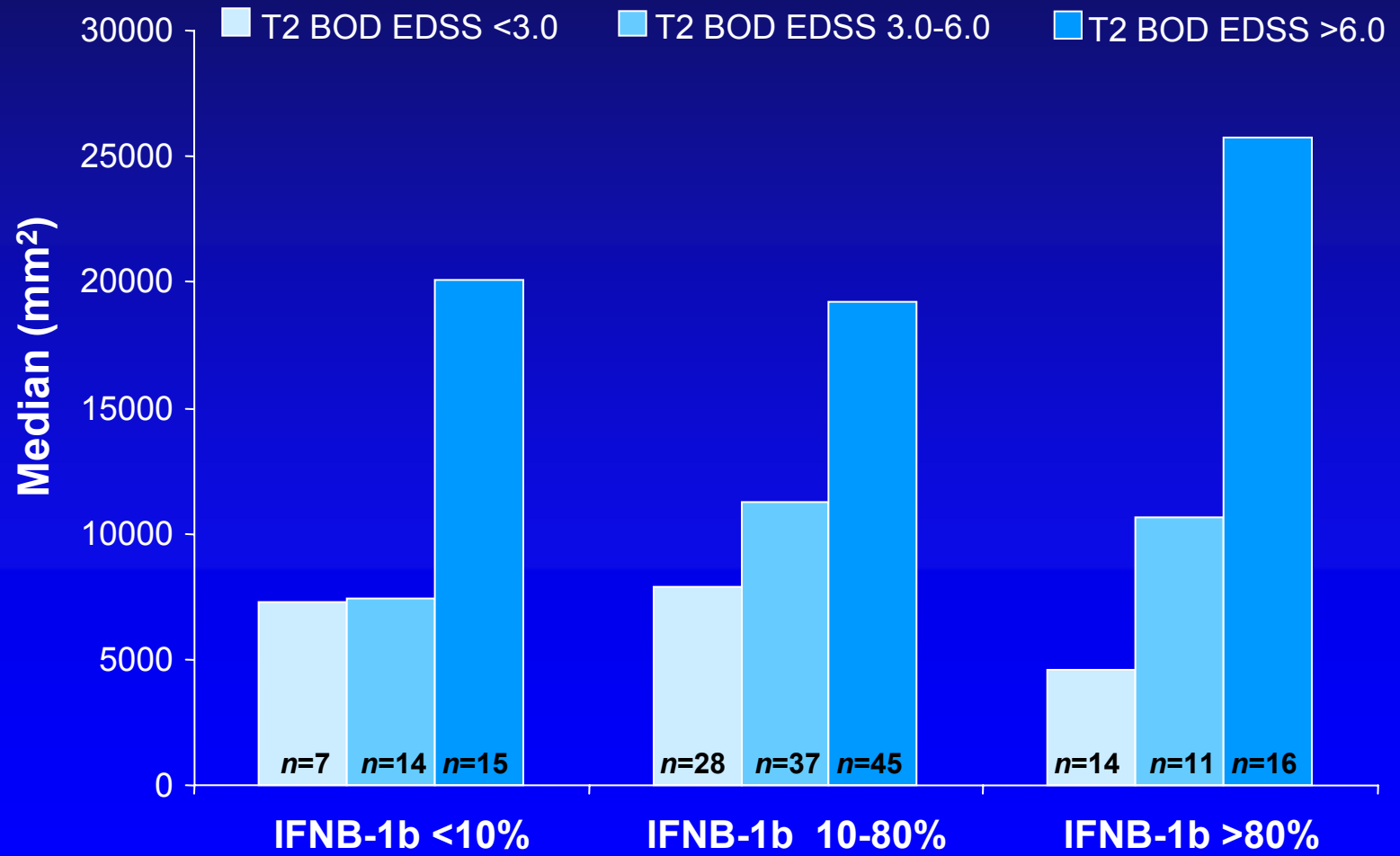


Not including deceased patients

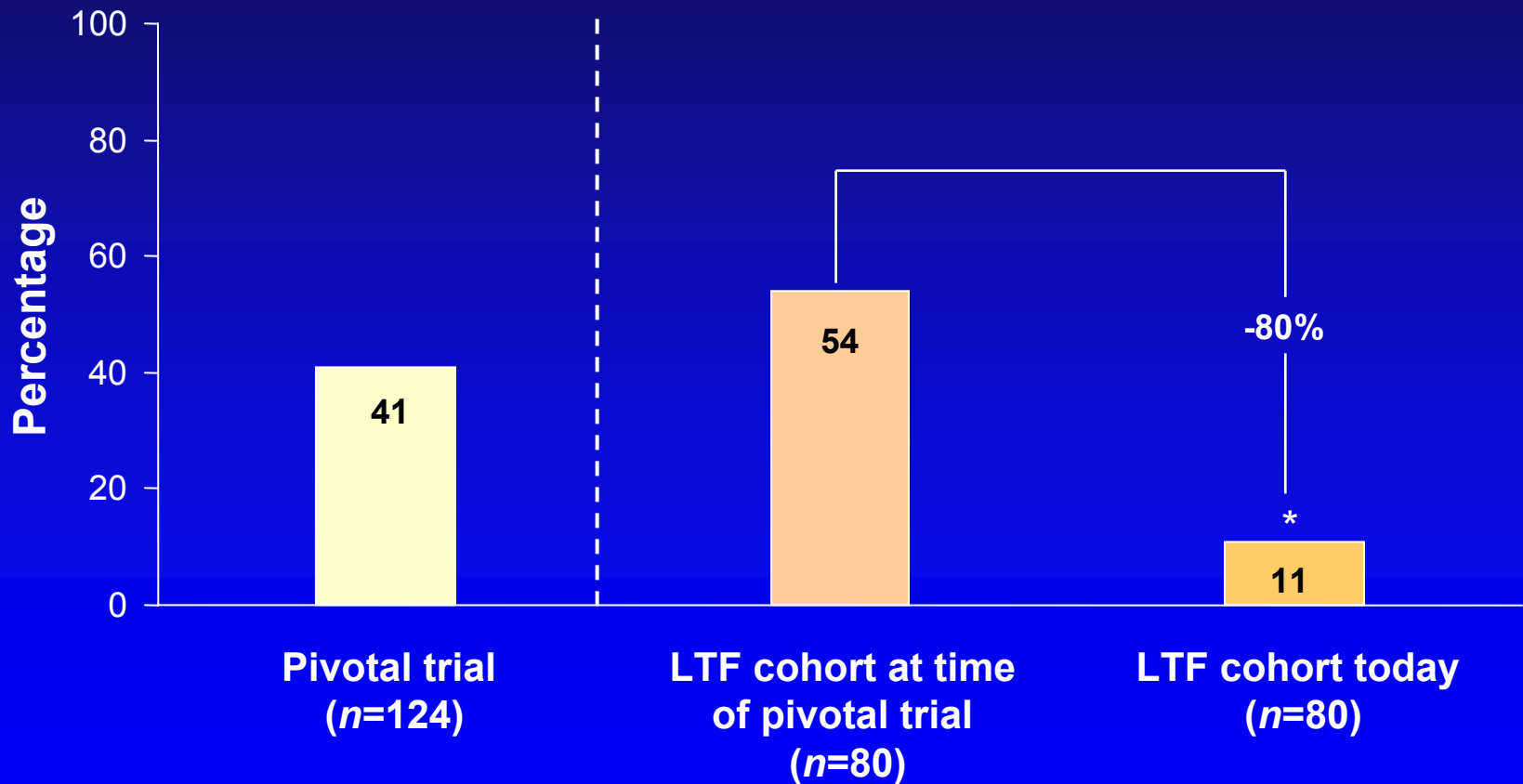
Reduction in Annualized Relapse Rate is Maintained on Long-term Treatment With Betaseron®



Correlation Between Increase in T2 Burden of Disease and Worsening EDSS Score



Reduction in Number of NAb-positive Patients Over Long-term Treatment with Betaseron® (250 µg groups)



*Not correlated for potential other IFNB use

Summary

- Despite the long interval, it was possible to locate almost 90% of patients from the pivotal trial
- After 16 years the long-term safety of Betaseron[®] appears to be excellent
- The median treatment duration of the whole patient cohort is almost 10 years, which indicates high adherence to Betaseron[®] therapy
- Results suggest that early treatment and continuous long-term therapy may have an advantage
- Additional analyses will compare the results from patients in this cohort with expected outcomes based on natural-history data