

Impact of IPX203 (CREXONT®) on Parkinson's patients' motor states upon awakening: analysis of patient diary data

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Background

- IPX203 (CREXONT®) is a novel extended-release, oral carbidopa-levodopa (CD-LD) formulation that provides fast onset and prolonged duration of "On"
- In the RISE-PD trial, patients on CREXONT- dosed 2-4 times per day - demonstrated significantly more "Good On" time per day and "Good On" time per dose compared to IR CD-LD¹

Objective

- To evaluate "On" upon awakening in patients with Parkinson's disease (PD) taking CREXONT in the RISE-PD phase 3 clinical trial

Methods

- RISE-PD was a randomized, double-blind, active-controlled phase 3 study of the safety and efficacy of CREXONT vs IR CD-LD in patients with PD experiencing motor fluctuations (**Figure 1**)
- The study had a 3-week open-label IR CD-LD dose adjustment phase and a 4-week open-label dose conversion phase to CREXONT, followed by a 13-week, double-blind, double-dummy maintenance phase with IR CD-LD or CREXONT
- We performed an analysis of Hauser diary data from the 495 subjects that completed the RISE-PD study (modified intent-to-treat [mITT] analysis set)
- The following outcome measures were evaluated over the three days prior to the study visit utilizing mixed model repeated measures (MMRM) analysis:
 - the percentage of times waking up "On" ("On" upon awakening)
 - the percentage of patients that never recorded "Off" upon awakening
 - the percentage of patients that never recorded "On" upon awakening

Higher proportion of patients recorded "On" upon awakening with CREXONT treatment compared to IR CD-LD.

Figure 1. RISE-PD Study Design¹

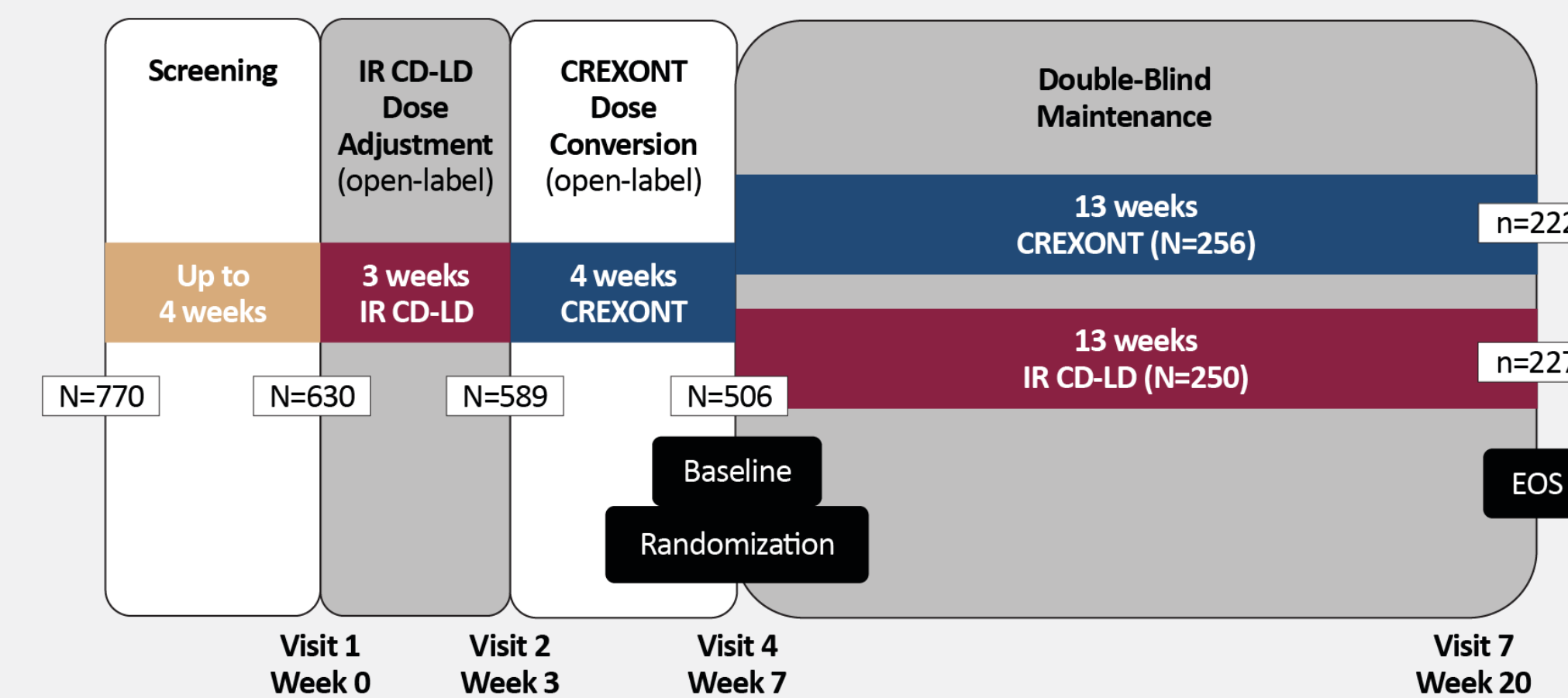
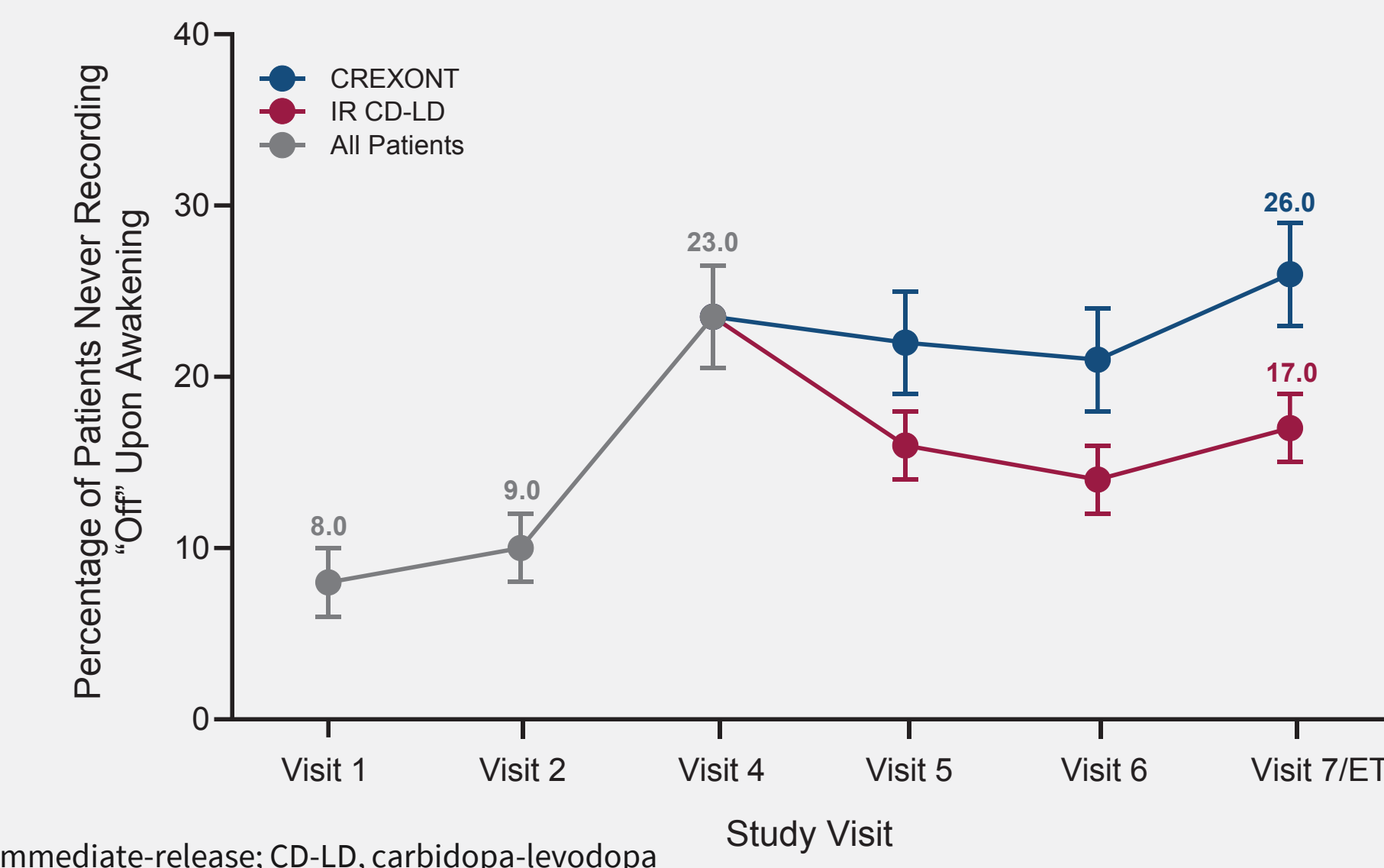


Figure 3. Percentage of Patients Never Recording "Off" Upon Awakening



IR, immediate-release; CD-LD, carbidopa-levodopa

Figure 2. Percentage of Times Waking Up "On"

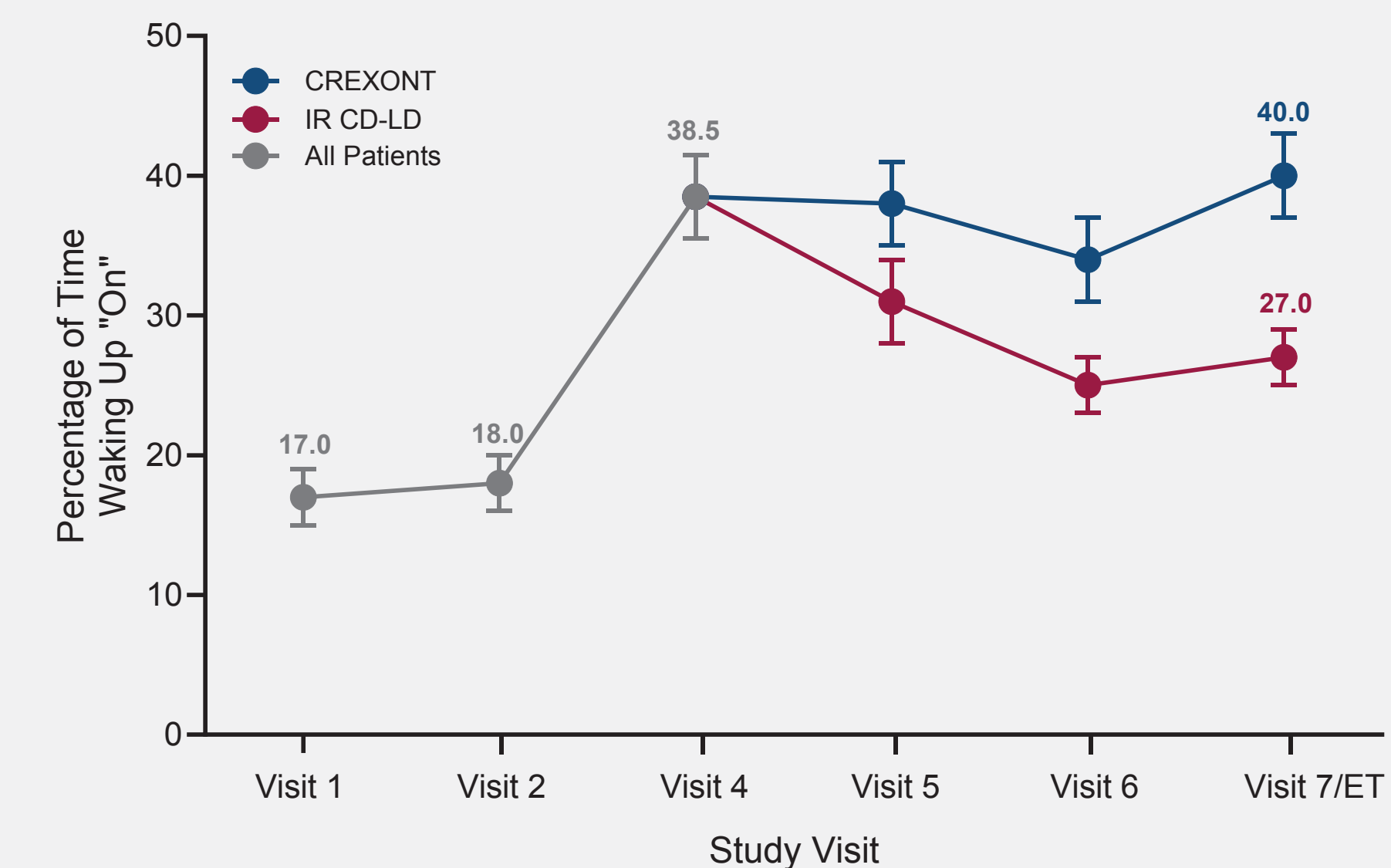
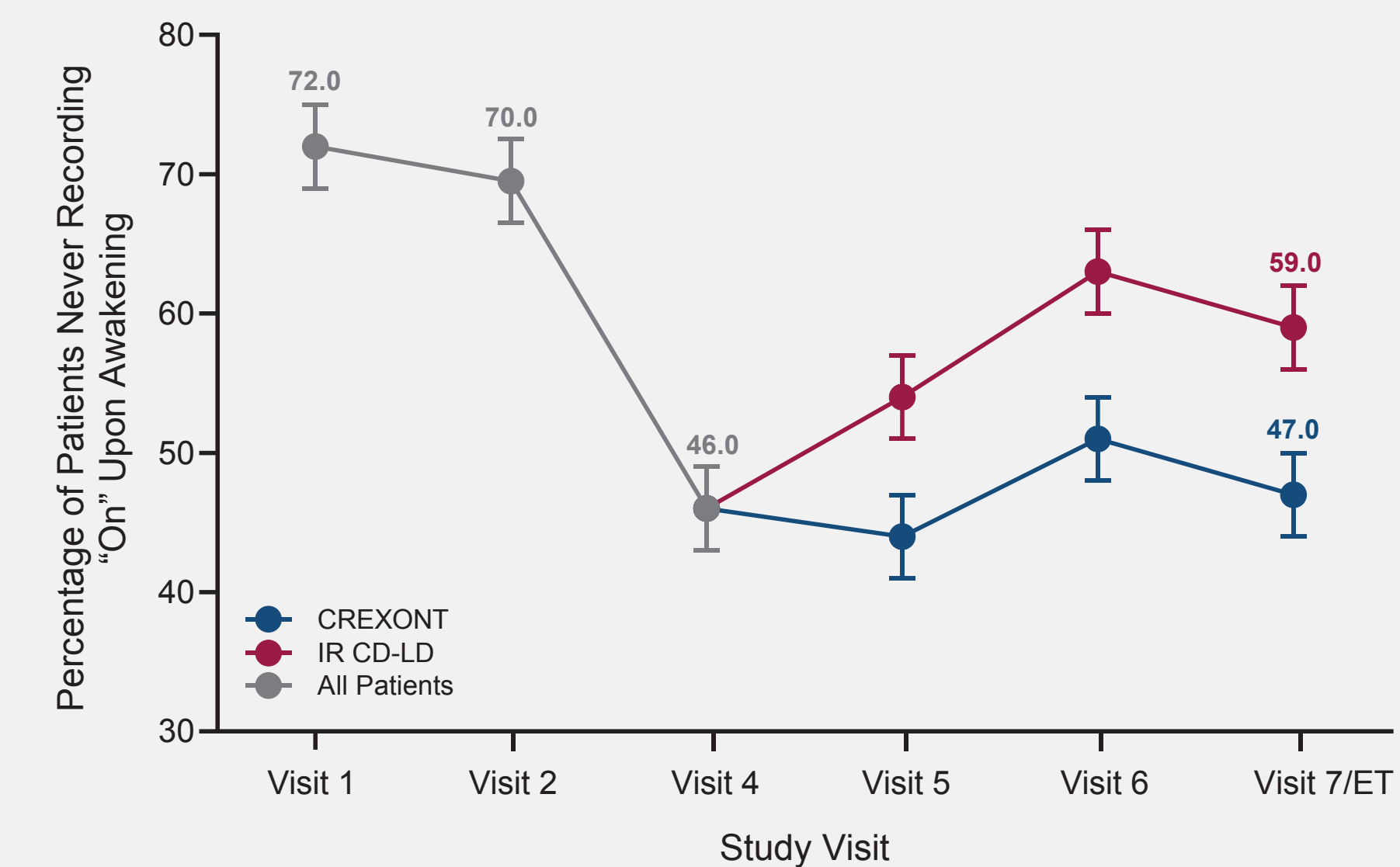


Figure 4. Percentage of Patients Never Recording "On" Upon Awakening



Results

- At study entry, patients recorded "On" upon awakening 17% of the time. At end of study (EOS), 40% of patients on CREXONT vs 27% of patients on IR CD-LD recorded "On" upon awakening ($P=0.0004$) (**Figure 2**)
- At study entry, 8% of patients never recorded "Off" upon awakening. At EOS, 26% of patients on CREXONT never recorded "Off" upon awakening vs 17% in the IR CD-LD group ($P=0.0224$) (**Figure 3**)
- At study entry, 72% of patients never recorded "On" upon awakening. At EOS, 47% of patients on CREXONT never recorded "On" upon awakening (25% decrease) vs 59% in the IR CD-LD group (13% decrease) ($P=0.0067$) (**Figure 4**)

Conclusions

- CREXONT treatment resulted in a significant increase in patients waking up "On" during the study period
- At EOS, a significantly higher percentage of patients on CREXONT were never "Off" upon awakening compared to patients on IR CD-LD
- Significantly lower percentage of patients recorded to never be "On" upon awakening in the CREXONT group vs IR CD-LD

REFERENCE

1. Hauser RA, et al. *JAMA Neurol.* 2023;80(10):1062-1069.

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