

Study Endpoints

- The primary endpoint was the annualized rate of IRAEs, i.e. the total number of events occurring during the extension phase per patient-year of drug exposure during the extension phase
 - Assessments of IRAEs (including all local injection-site reactions [ISRs] or events related to immediate post-injection reaction) were performed during the extension phase based on the patient's diary card recordings of events and severity
 - Severity was defined as shown in **Box 1**
 - All IRAEs occurring in the active treatment phase were coded to MedDRA preferred terms
- The secondary endpoint was change in assessment of patient perception of treatment convenience, using the convenience-specific subscale (items 4–6) of the VAS as measured every 4 months from extension phase baseline (**Box 2**)
 - Higher scores represented more positive perceptions of treatment
- Additional endpoints included the rate of ISRs, subject-reported impact on psychological well-being using the Multiple Sclerosis Impact Scale-29 questionnaire, and subject perceptions of overall satisfaction using the TSQM-9 subscale (items 1–5)

Study Methodology

- The last observed post-baseline data were used for endpoint visit analysis during the extension phase
 - For patients who withdrew from the study, data at the ET visit were included in endpoint visit analysis, with the exception of MSIS-29 and TSQM-9 questionnaires for which the ET visit was considered as the next scheduled visit

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