Study Endpoints

- The primary endpoint was the annualized rate of IRAEs, i.e. the total nu
  events occurring during the extension phase per patient-year of drug e
  the extension phase
  — Assessments of IRAEs (including all local injection-site reactions [ISR
    or events related to immediate post-injection reaction) were perforn
    the extension phase based on the patient's diary card recordings of
    and severity
  — Severity was defined as shown in **Box 1**
  — All IRAEs occurring in the active treatment phase were coded to Me
    preferred terms
- The secondary endpoint was change in assessment of patient perceptic
  convenience, using the convenience-specific subscale (items 4–6) of the
  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
  psychological well-being using the Multiple Sclerosis Impact Scale-29 questic
  and subject perceptions of overall satisfaction using the TSQM-9 subscale (it

Study Methodology

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