beta-1b (interferons) and natalizumab and the reactions suspected of being associated with them were identified. Disproportionality analyses used the Multi-Item Poisson Regression method with WHO-ART diagnosis to set the preferred term level for all AEs and for the standard combination of all WHO ‘critical terms’. Statistical significance for disproportionality was defined as an Empirical Bayesian Geometric Mean lower fifth percentile (EBGM05) >2.0. Comparisons were made between GA versus other drugs and GA versus interferons and natalizumab. Sales data for GA were available to calculate reporting rates. RESULTS: A total of 2,320 cases with 6,680 AEs with a suspected relationship with GA and 20,155 cases with 72,326 AEs for interferons and natalizumab were identified. Compared with all other drugs in Vigibase and with interferons and natalizumab, GA was associated with several statistically significant observations of disproportionate reporting. In a risk-benefit analysis of GA based on traditional meta-analysis, the number of AEs with several statistically significant observations of disproportionate reporting. Thus, a situation analysis of a global large spontaneous AEs database permitted the calculation of reporting rates. For example, the reporting rate of WHO ‘critical terms’ combined were not higher for GA versus interferons and natalizumab (EBGM 0.84 90% credibility interval 0.79-0.90). The reporting rate of WHO ‘critical terms’ was 68 events/100,000 person-years. CONCLUSION: In a risk-benefit analysis of GA based on traditional meta-analysis, the number of AEs with several statistically significant observations of disproportionate reporting.VALIDATION OF THE INTRAVENOUS FABRINAPIDE Efficacy in Comparison With Usual Care in the Treatment of Multiple Sclerosis OBJECTIVES: The aim of this study was to evaluate the effectiveness of a French neurologist collected analytic data on 405 patients. After review by experts, patients were finally classified as FR in 80% (76.6%) of them, in 91 (22.4%) as responsive and in 28 (7%) as undefined. The mean annual Cost of Corticosteroid-Associated Adverse Events in Systemic Lupus Erythematosus

OBJECTIVES: To estimate costs of managing corticosteroid (CS)-related adverse events (AEs) within a systemic lupus erythematosus (SLE) population. METHODS: A retrospective review of medical records of SLE patients aged 18 years or older within an SLE population to evaluate the risk of known CS-related chronic and acute AEs among CS users and non-users by utilizing Cox proportional hazards models adjusting for patient characteristics, SLE severity, other SLE treatments, and AEs-related therapies. AEs were recorded for patients requiring corticosteroids for at least 12 months. RESULTS: In the Cox model, the cumulative incidence of CS-related AE was greater for CS users compared to non-users (hazard ratio 1.36, 95% confidence interval 1.01-1.85). In a sensitivity analysis including only patients with high CS doses, the cumulative incidence of CS-related AE was greater for CS users compared to non-users (hazard ratio 1.51, 95% confidence interval 1.16-1.96). CONCLUSIONS: CS is associated with an increased risk of CS-related AEs among CS users compared to non-users. The increased risk of CS-related AEs is particularly high among patients with high CS doses. Further research is needed to identify risk factors for CS-related AEs among CS users.