Due to its complexity, it is not always possible to assess many of the symptoms and treatment effects associated with SLE using objective clinical measures. The clinical presentation of SLE varies greatly from patient to patient. In the US, it is estimated that 1 in 200 persons and SLE is much more frequent among women than men, with a ratio of 9:1. As evidenced by the broad spectrum of criteria for diagnosis, the importance of also taking into account the patient perspective in clinical trials using validated and reliable patient-reported outcome (PRO) measures.

Patient-reported outcomes provide unique and important information on the impact of systemic Lupus Erythematosus (SLE) on daily lives of patients. It fosters patient-physician communication, patient engagement and satisfaction with medical care, and opportunity to provide comprehensive patient evaluation. Patient reported outcomes provide important information on the impact of systemic lupus erythematosus (SLE) on daily lives of patients. It also supports patient-physician communication, patient engagement and satisfaction with medical care, and opportunity to provide comprehensive patient evaluation. Lupus Patient-Reported Outcome (LupusPRO) is a disease targeted patient reported outcome tool that has good measurement properties and has been validated in several languages and countries. The tool was developed using feedback from male and female SLE patients with varied ethnic backgrounds, and includes a comprehensive assessment in health and non-health areas of quality of life.

Purpose
The aim of this study was to assess the validity and reliability of the Italian translation of the LupusPRO. Herein we report the measurement properties of an online version of the questionnaires that was administered using a web-based format.

Methods
LupusPRO was translated using forwards and back translation method into Italian language. It was translated into 5 native Italian speaking subjects. Feedback was used to finalize the translated version. As part of another research, 344 patients with self-report of SLE diagnoses were approached through the Italian Lupus Patients organization network, asked to provide their demographics, medications and responses to the online LupusPRO. LupusPRO is a disease-specific questionnaire with a 5-point Likert response format, from 0 (none of the time/not applicable) to 4 (all of the time). There are 12 subscales: Lupus Symptoms, Coping, Lupus Medications, Prophylactic, Physical Vitality, Emotional Health, Body Image, Daily Activity, Social support, Coping, Satisfaction with care. Item scores are totaled for each domain item and the mean domain score is obtained by dividing the total score by the number of items in that domain. Following the guidelines, the final scores were transformed to scores ranging from 0 (worst QOL) to 100 (best QOL) and were combined into a summary score. We evaluated internal consistency reliability (ICR) of the LupusPRO domain items, floor-covering effects, known groups validity (KGV) and confirmatory factor analysis (CFA). ICR was tested using cronbach’s α estimation. KGV was tested against current use of corticosteroids, with the hypothesis that SLE patients currently on corticosteroids would have worse health status than without. Goodness of fit was evaluated in the CFA. All p-values are on two tailed test with α = 0.05 being considered statistically significant.

Results
Mean (SD) age was 38.7 (11.1) years. The duration of disease was 11.7 (5.3) years. Fifty-four percent were on corticosteroids and sixty-six percent were on hydroxychloroquine at the time of the study. In line with the estimates of SLE prevalence, 32.7% of the sample were males. In all, 18.6 percent had a qualification lower than high school diploma, 74 percent were high school graduates, 11.6 percent had a bachelor’s degree, and 14 percent had a master’s degree. As regards marital status, 49.7 percent were married, 36.6 percent were unmarried, 10.8 percent were divorced, and 2.9 percent widows/widowers. In all, 31.1 percent were working full-time, 17.7 percent part-time work, 11.4 percent self-employed, while 43.4 percent were not working (unemployed 10.8%, housewife 11.3%, retired 7.6%, unable to work 4.7%).

Mean (SD) LupusPRO domain scores, ICR, floor-covering effects and KGV are shown in Table 1. The hypothesis about corticosteroids was supported for many subscales: SLE patients currently on corticosteroids showed worse health status than without. On CFA, with few exceptions the items correlated highly (r > 0.5) with their hypothesized scales. The CFI was 0.93 and TLI was 0.97 (both are considered good models) [8]. The mean square error of approximation (RMSEA) was 0.003 (a 0.1 is considered acceptable).

Conclusion
Web version of LupusPRO Italian translation shows fair psychometric properties in Systemic Lupus Erythematosus patients. Compared to some previous validations (e.g. Spanish [9]), the Italian on-line translation showed lower rates in some scales, like Satisfaction with Medical Care (65.6 Vs. 100). Such differences should be carefully considered in the light of samples’ characteristics and of the procedure (paper in clinical settings Vs. online). The latter, even if compiled in a not-controlled setting (online), would reduce the possible confounding effect of social desirability factors.

References