Overview of COA measures in SLE clinical trials and label claims

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Background

Systematic lupus erythematosus (SLE) is a condition linked with high symptom burden and severe quality of life (QoL) impacts. The FDA and EMA SLE guidance recommends inclusion of clinical outcome assessments (COAs), such as those assessing disease activity, fatigue, and quality of life in SLE clinical trials. The objective of this review is to review the landscape of COAs that were included in SLE clinical trials and FDA and EMA drug labels.

Methods

The PROLABELS database was reviewed to identify COA-related label claims for approved SLE products (FDA and EMA). The data base was searched for all results relating to "Lupus erythematosus, systemic"; results were not limited to a single timeframe. A review of the Clinicaltrials.gov website was also performed to identify COAs used in SLE clinical trials in the past 10 years. Search criteria for "SLE" and "systemic lupus erythematosus" were used; the review was limited to trials that met the following limits: (1) completed, (2) interventional, (3) Phase III, and (4) conducted in the past ten years.

Results

Three drug approvals with COAs included in the label were identified via the PROLABELs database. Two approvals were granted by the EMA (Benlysta, 2011 and Saphnelo, 2022) and one was also approved by the FDA (Benlysta, 2011). Fatigue was the only PRO , while the rest included ClinROs assessing flares and disease activity. A total of eleven clinical trials meeting the criteria were identified. Five included PROs and nine included ClinROs used to support primary and secondary endpoints. The most frequently utilized PROs (primary and secondary endpoints) in clinical trials were the Functional Assessment of Chronic Illness Therapy (FACIT-Fatigue) (n=3), and Lupus Quality of Life Questionnaire (LupusQoL) (n=2). The majority of ClinROs used supported primary composite endpoints for disease activity.

Figure 1. Overview of SLE drug approvals

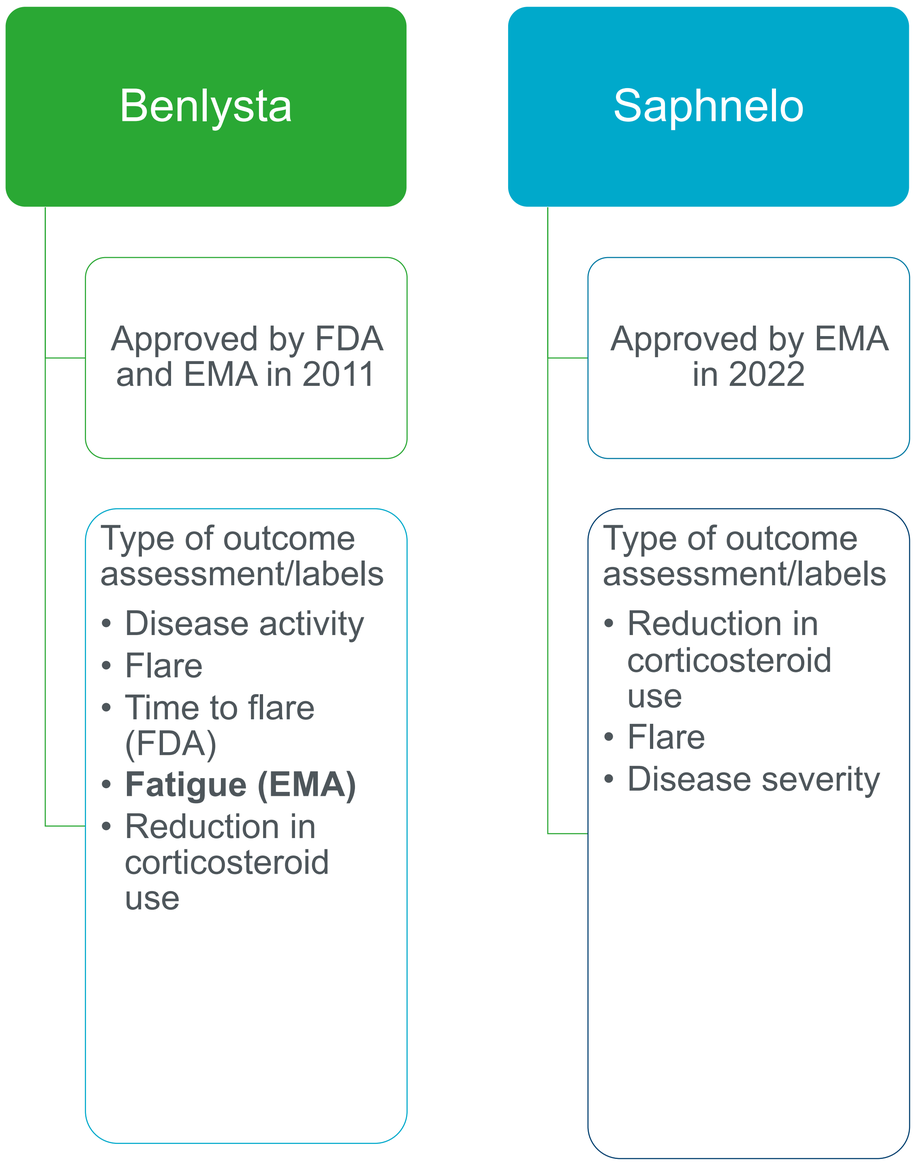
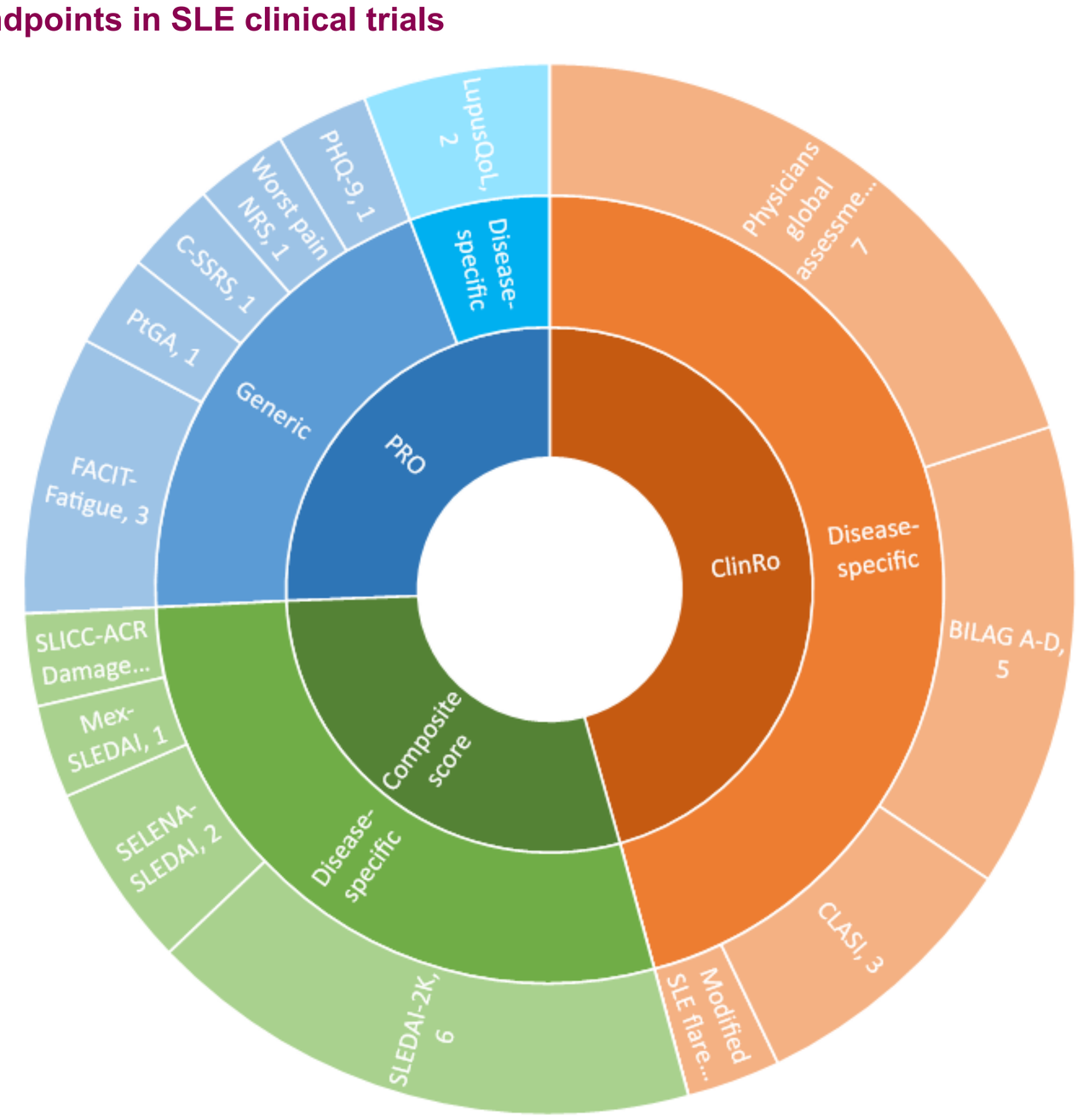


Figure 2. COAs previously used to support primary and secondary endpoints in SLE clinical trials



Conclusions

The review of labels for approved SLE drugs indicated only a single drug that included a PRO in the label. PROs in SLE trials were not consistently used and unlikely assessed all meaningful outcomes. Future SLE drug development should focus on improving meaningful outcomes for patients, especially those relating to QoL impacts.

References