EASI Data Visualization: A New Interactive Tool to Evaluate the Efficacy of Drugs by EASI Clinical Sign and Body Region Using Example Data from a Phase 2b Study of Lebrikizumab in Atopic Dermatitis

Jonathan I. Silverberg, (Presenter)[1] Peter A. Lio,[2] David Rosmarin,[3] Luna Sun,[4] Maria Jose Rueda,[4] Deepak Krishna Lola[4]

[1]George Washington University School of Medicine and Health Sciences, Washington, DC, USA; [2] Northwestern University Feinberg School of Medicine, Chicago, IL, USA; [3]Tufts Medical Center, Boston, MA, USA; [4] Eli Lilly and Company, Indianapolis, IN, USA

Background: The Eczema Area and Severity Index (EASI) is the preferred outcome measure for clinical signs of AD in clinical trials. Though EASI total score is a composite based on the evaluation of signs (redness, swelling, scratching, lichenification), area, and severity in each of four body regions, it is reported as a single number. Thus, the total score alone gives no indication of the weight of the driving forces behind it. The EASI Data Visualization tool is a custom designed, dynamic and interactive web-based application allowing in-depth visualization of each skin sign by body regions. The tool facilitates rapid dermatological evaluation of the intensity and extent of lesion involvement in patients with AD participating in clinical trials. We use lebrikizumab phase 2b data to demonstrate the functionality of the tool.

Methods: EASI Data Visualization illustrates changes in EASI total score components over time. The web-based application features responsive design which can render well on tablets, phones, and laptops. EASI Data Visualization is intended to communicate data entered by the clinical trial sponsor using visual elements for enhanced accessibility. We utilized data from a randomised, placebo (PBO)-controlled, double-blind, phase 2b study (NCT03443024). This analysis includes data from two treatment arms: patients receiving lebrikizumab 250mg every 2 weeks (Q2W) following a loading dose of 500 mg at baseline and Week 2, and patients receiving PBO Q2W, for 16 weeks. The primary endpoint of the trial was the percent change from baseline (%CFB) in EASI total score to Week 16. Full EASI data including each component are available through EASI Data Visualization. Here, we use EASI lichenification in the trunk region to demonstrate how the tool can be used to visualise data. Last observation carried forward was used for imputation.

Results: A total of 280 patients were randomised, and of these, 75 received lebrikizumab 250 mg Q2W and 52 patients received PBO Q2W. The EASI total score mean %CFB at Week 16 was -72.8% for lebrikizumab 250 mg Q2W, and -40.6% for PBO. The EASI lichenification of the trunk %CFB at Week 16 was -59.4% for lebrikizumab 250 mg Q2W, and -34.7% for PBO.

Conclusions: EASI Data Visualization offers a visual representation of disease severity and allows for rapid and comprehensive interpretation of each component of the EASI total score. The accessibility of the application allows clinicians to better understand the data collected in clinical trials at their convenience.

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