Subjective Measures, Objective Outcomes: Data Quality in Atopic Dermatitis Trials

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Introduction

Atopic Dermatitis (AD) is one of the most prevalent skin conditions worldwide. In recent years, there has been significant activity in the AD clinical trial landscape, including the approval of novel systemic therapies. Accurate measurement of AD severity over time is crucial for evaluating treatment efficacy in these trials. This blog post explores the key measurement tools used in AD trials, specifically the Eczema Area and Severity Index (EASI) and Total Body Surface Area (BSA), and discusses strategies for improving data quality.

The Importance of Accurate Measurement

Evaluating the severity of AD in clinical trials is essential for understanding the effectiveness of treatments. The Harmonizing Outcome Measures for Eczema (HOME) group has defined a core set of outcomes for AD trials (Williams et al., 2022). However, protocols often include additional instruments that may overlap in the aspects of the disease they measure. Understanding how these instruments work and their potential for subjectivity is critical for maintaining high data quality.

Key Measurement Tools: EASI & BSA Methods

The EASI and Total BSA are frequently utilized as primary and secondary endpoint measures in AD clinical trials. The Total BSA measures the extent of skin involvement with AD as a percentage, using methods like the rule of nines (BSA_R9) or the palmar method. This involves either dividing the body into sections representing 9% BSA each or measuring disease extent using the size of the patient as a reference.

The EASI, on the other hand, includes additional measures of disease severity, such as erythema, edema or papulation, excoriation, and lichenification. It calculates the extent of disease across different body regions and converts it to an overall percentage body surface area (EASI_BSA) affected.

In these ways, the two assessments measure BSA quite differently. When collecting simultaneous endpoint measures in a trial, it is important to consider how they fit together. Will they help gain a clearer or more rounded understanding of study data? Or simply add noise and discordance?

Comparing Measurement Methods

Signant Health studied differences in measuring the percentage of BSA involvement in AD using the BSA_R9 and EASI_BSA. In a sample of 660 EASI_BSA and BSA_R9 scores collected across 170 patients, approximately 20% of BSA_R9 scores fell outside the range of EASI_BSA involvement. In 60% of those cases, the BSA_R9 score was higher than the EASI_BSA upper limit, while 38% of BSA_R9 scores were lower than the EASI_BSA lower limit for the same visit.

These findings highlight the importance of knowledgeable interpretation of scale measurements, as each instrument can portray a different extent of treatment efficacy.

Improving Measurement Reliability

Measurement standardization continues to challenge dermatology clinical trials. Using multiple independent measures can support reliable assessment of AD severity (Bożek & Reich, 2017). Experts have also evidenced the benefit of rater training in supporting reliable disease assessment (Armstrong et al., 2013; Everhart & Kalpadakis-Smith, 2021; Youn et al., 2015). Signant's research has shown that standardizing rater training can greatly improve data quality of subjective ClinROs in dermatology clinical trials.

In addition to rater training, data analytics can further support endpoint quality monitoring by detecting variability patterns in contrast with known disease progression.

Conclusion

Accurate measurement of AD severity is essential for the success of clinical trials. Understanding the differences between tools like EASI and BSA, and implementing strategies such as standardization and rater training, can significantly improve data quality.

If you're interested in learning more about endpoint quality solutions for dermatology trials, contact us.

References

Armstrong, A. W., Parsi, K., Schupp, C. W., Mease, P. J., & Duffin, K. C. (2013). Standardizing training for psoriasis measures: effectiveness of an online training video on Psoriasis Area and Severity Index assessment by physician and patient raters. JAMA Dermatology, 149(5), 577-582.

Bożek, A., & Reich, A. (2017). Assessment of intra-and inter-rater reliability of three methods for measuring atopic dermatitis severity: EASI, objective SCORAD, and IGA. Dermatology, 233(1), 16-22.

Everhart, A., & Kalpadakis-Smith, A. (2021). Properly Training Physicians in Dermatology Trials. https://www.appliedclinicaltrialsonline.com/view/properly-training-physicians-in-dermatology-trials

Silverberg, J. I., Simpson, B., Abuabara, K., Guttman-Yassky, E., Calimlim, B., Wegzyn, C., & TARGET-DERM Investigators. (2023). Prevalence and burden of atopic dermatitis involving the head, neck, face, and hand: A cross sectional study from the TARGET-DERM AD cohort. Journal of the American Academy of Dermatology, 89(3), 519-528.

Williams, H. C., Schmitt, J., Thomas, K. S., Spuls, P. I., Simpson, E. L., Apfelbacher, C. J., Chalmers, J. R., Furue, M., Katoh, N., Gerbens, L. A. A., Leshem, Y. A., Howells, L., Singh, J. A., Boers, M., & HOME Initiative (2022). The HOME Core outcome set for clinical trials of atopic dermatitis. The Journal of Allergy and Clinical Immunology, 149(6), 1899–1911.

Youn, S. W., Choi, C. W., Kim, B. R., & Chae, J. B. (2015). Reduction of inter-rater and intra-rater variability in psoriasis area and severity index assessment by photographic training. Annals of Dermatology, 27(5), 557.

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