

# Changes in Urticaria Symptoms, Dermatologic-Related Quality of Life, and Urticaria-Specific Quality of Life: are they telling us the same thing about response to treatment for chronic spontaneous/idiopathic urticaria (CSU/CIU)?

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## INTRODUCTION

- CSU is defined by the latest EAACI/GA2LEN/EDF/WAO\* guidelines as the occurrence of wheals (hives), angioedema or both for 6 weeks or longer due to known or unknown causes (1)
- It impacts different domains of patients health related quality of life (HRQoL) such as ability to perform daily tasks, sleep disturbance, loss of energy, emotional distress etc. (2,3)
- The progression of disease and its burden can be assessed with patient-reported outcomes (PRO) measures for symptoms and HRQoL
- Different types of PROs might not have a similar sensitivity and specificity in detecting fluctuations in disease activity reflected by progression of symptoms and signs, HRQoL, and impact of treatment benefit
- There is a lack of evidence available about whether these measures provide similar information to clinicians about patient's condition and changes in their urticaria
- Innovative analysis of evaluating the correlation of change across all assessment points for each patient, irrespective of treatment, allows direct comparison of changes in each PRO

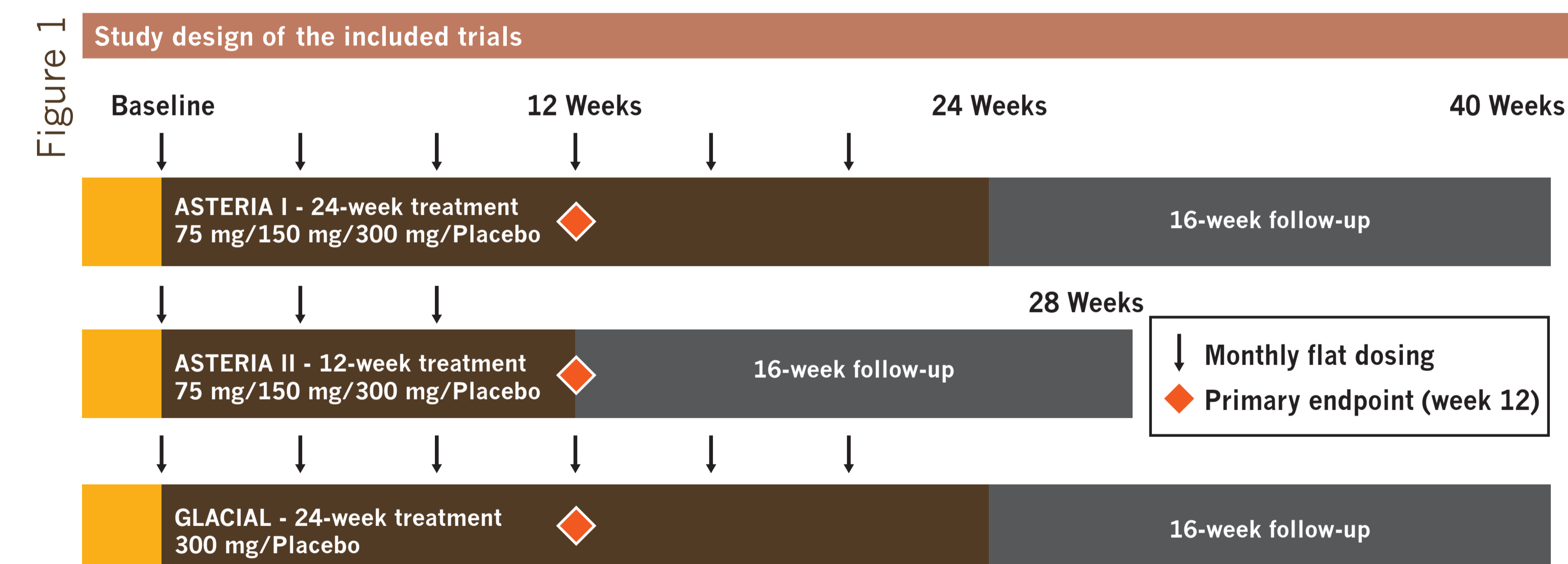
## OBJECTIVE

- The objective of the current analysis was to assess whether three PRO measures are equally informative about response to treatment of patients with CSU/CIU
- The PRO measures below were compared to see if they provide comparable information about patients' symptoms and status at the start of clinical trial and changes in their condition over the course of the trial:
  - Urticaria Activity Score (UAS) (4)
    - A patient diary measuring daily pruritus and number of hives scores summed over 7 days for a weekly score (UAS7)
    - Scores range from 0-42 with higher scores meaning more severe urticaria
  - Dermatology Life Quality Index (DLQI) (5)
    - 10-item PRO with one-week recall assessing the impact of skin disease on patients
    - Scores range from 0-30, with higher scores reflecting worse dermatologic QoL
  - Chronic Urticaria Quality of Life (CUQ2oL) (6)
    - 23-item PRO with 2-week recall measuring urticaria-specific QoL through rating of symptoms and their impact on aspects of life
    - Scores range from 0-100, with higher scores indicating worse QoL

## METHODS

### Data

- Data come from three pivotal phase III clinical trials (ASTERIA I, ASTERIA II and GLACIAL) investigating the effects of omalizumab in patients with refractory CSU/CIU aged 12-75 years. The study design of the trials is presented in **Figure 1**



- The UAS7 scores were calculated at baseline, week 4, 8, 12, 16, and 20 during the treatment period; and at week 24, 28, 32, 36, and 40 in the follow-up period (ASTERIA I and GLACIAL) and at baseline, week 4, 8 and 12 during the treatment period; and at week 16, 20, 24, and 28 in the follow-up period (ASTERIA II)
- The DLQI and CUQ2oL were administered at baseline, week 4 and 12 during the treatment period; and at week 24 and 40 in the follow-up period (ASTERIA I and GLACIAL) and at baseline, week 4 and 12 during the treatment period and at week 28 in the follow up period (ASTERIA II)
- Data from the same time points for all PROs were used for the analysis which was conducted for each trial separately

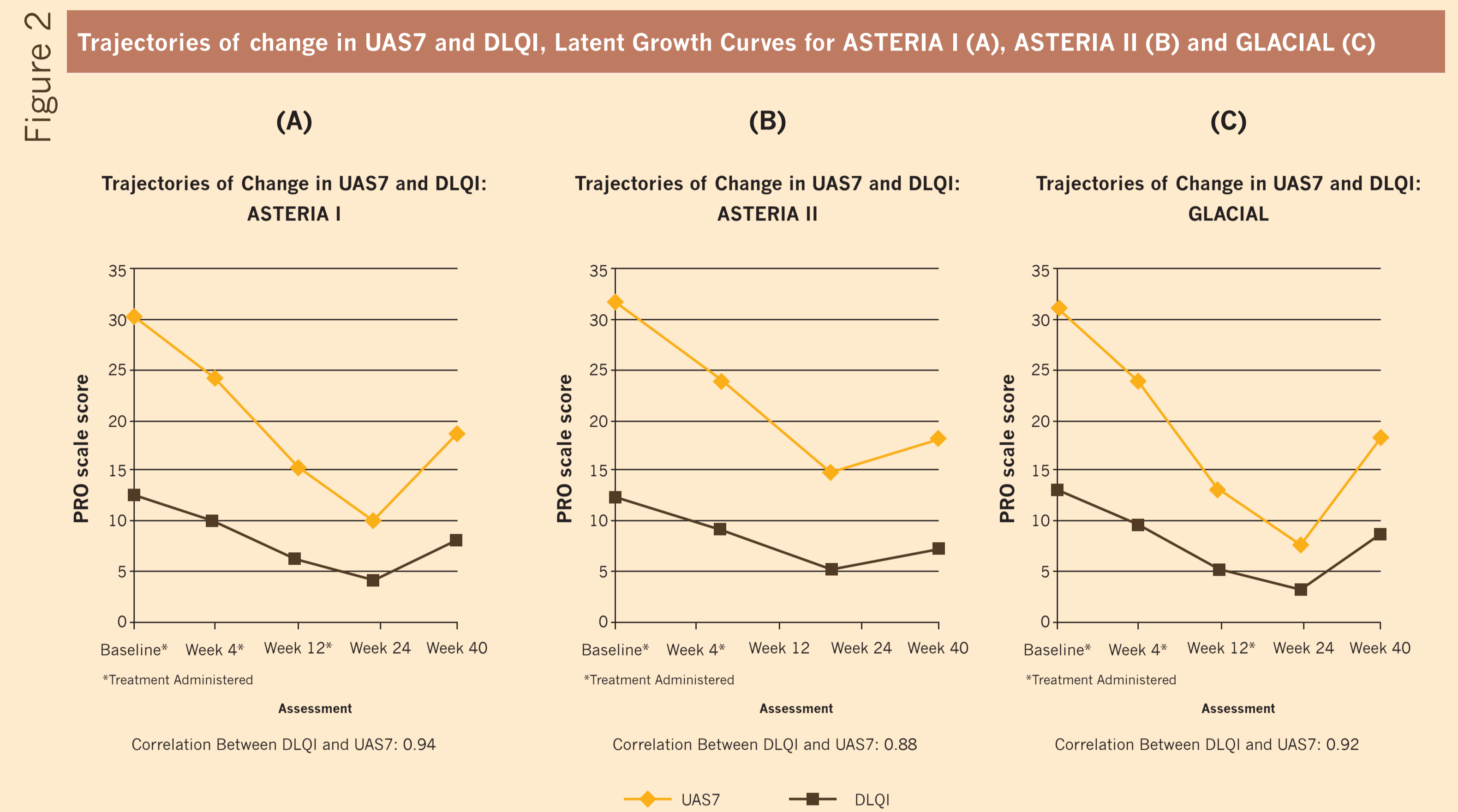
### Analytic Methods

- Data from all 3 studies were analyzed using a growth curve analysis known as latent growth modelling to evaluate changes across all assessment points for each patient, irrespective of treatment, allowing direct comparison of change in one variable with change in another

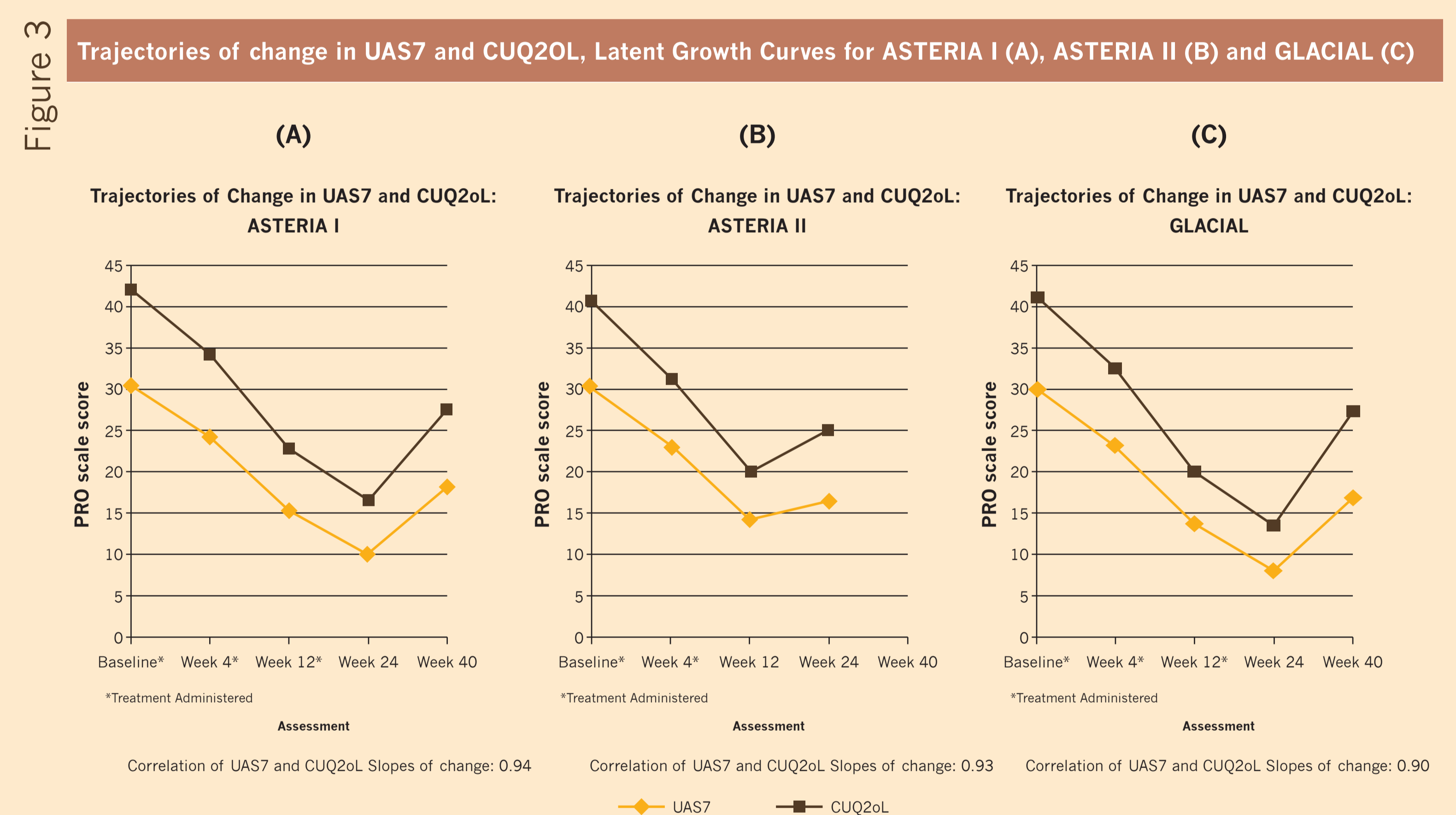
- Unlike analyses that compare mean changes between groups of patients, latent growth models (LGMs) calculate an intercept and slope of change for each patient for each PRO and allow the intercepts and slopes of change to be correlated (7)
- Both an intercept and a slope of change in responses are generated for each individual within the data set. The intercept variable is the value of the growth curve at the first assessment point. This value is similar but not equivalent to the value of the initial observation for a respondent
- The correlations will indicate the strength of association between changes in UAS7 and changes in the other PROs and will investigate how closely changes in urticaria signs and symptoms are reflected in changes in general dermatologic-related and urticaria-specific QoL
- The greater the correlation between a patient's slopes of change in PRO outcomes, the greater would be the similarity in what these instruments are assessing

## RESULTS

- In all the three trials, the correlations between the UAS7 and DLQI ranged between 0.88 and 0.94 [Figure 2(A), (B), (C)]
- This indicates a near perfect association between the changes in signs and symptoms (UAS7) and dermatologic quality of life (DLQI); i.e., for each standardized unit change in UAS7 score, their score on DLQI would be changed by nearly the same standardized amount



- In all the three trials, the correlations between the UAS7 and CUQ2oL ranged between 0.90 and 0.94 [Figure 3(A), (B), (C)]
- This indicates a near perfect correspondence between changes in signs and symptoms and urticaria-specific QoL



## CONCLUSION

- The results provide clear evidence that any of the three PROs are suitable to evaluate the patient's severity of urticaria
- Regardless of what measure they use, clinicians will have comparable information about the evolution of patient's symptoms and signs, the changes in their HRQoL
- Improvements in symptoms, as measured by the UAS7 are reflected in improvements in HRQoL, as measured by the DLQI and the CUQ2oL
- The results further suggest that:
  - Collecting in-clinic DLQI and CUQ2oL data for the previous 7 days or 2 weeks will be indicative of the evolution of the symptoms in the same period
  - These are less likely to suffer from the potential data loss because of inconsistent completion of a patient's daily diary
- Collecting DLQI or CUQ2oL data could be easier to be implemented than a daily diary in some settings, such as in a clinician's office

\*EAACI: European Academy of Allergy and Clinical Immunology  
GA2LEN: Global Allergy and Asthma European Network  
EDF: European Dermatology Forum  
WAO: World Allergy Organization

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