

Psychometric Evaluation of the Facial and Total Vitiligo Area Scoring Index Instruments in the Topical Ruxolitinib Evaluation in Vitiligo (TRuE-V) Phase 3 Studies

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Supplementary Material Methods

F-VASI and T-VASI Evaluation

To determine the facial Vitiligo Area Scoring Index (F-VASI), the face was demarcated as including the forehead to the original hairline, the cheeks to the jawline vertically and laterally from the corner of the mouth to the tragus, the nose, and eyelids; the surface area of the lips, scalp, ears, and neck were excluded. Total Vitiligo Area Scoring Index (T-VASI) determination included all body regions and was calculated based on 6 separate and mutually exclusive sites (head/neck [including scalp], upper extremities [including axillae], hands, trunk [including genitalia], lower extremities [including buttocks], and feet).

In the TRuE-V studies, the area of depigmentation (affected body surface area [BSA]) was estimated by the investigator using the Palmar method (ie, hand units, where 1 patient hand unit represents approximately 1% total BSA). The degree of depigmentation for each site was determined and estimated to the nearest percentage: 100% (no pigment present), 90% (specks of pigment present), 75% (depigmented area exceeds the pigmented area), 50% (depigmented and pigmented areas are equal), 25% (pigmented area exceeds the depigmented area), 10% (only specks of depigmentation are present), and 0% (no depigmentation present; **Supplementary Material Figure 1**). F-VASI scores were derived by multiplying the BSA of the depigmented area by the percentage of depigmentation for the face (possible range, 0–3), and T-VASI was calculated using contributions from all body regions (possible range, 0–100).

Qualitative Exit Interviews

Qualitative interviews were conducted with patients who had recently completed the 24-week, double-blind treatment period, followed by interviews with patients who had recently completed

the 28-week extension period (Week 52). Interviews were conducted over the telephone and lasted approximately 60 minutes. Questions were asked regarding the impact of vitiligo on patients' lives and how improvements in facial and total body vitiligo and vitiligo noticeability influenced their lives and treatment satisfaction. Insights from the survey were used to classify patients as having a meaningful change after 24 weeks of the trial.

The interview transcripts were reviewed by 2 raters, and patients were classified as reporting clinically meaningful improvement, or not, from baseline. Any differences in classifications applied by the raters were discussed with a third expert, with this expert providing a final classification if the raters were unable to agree.

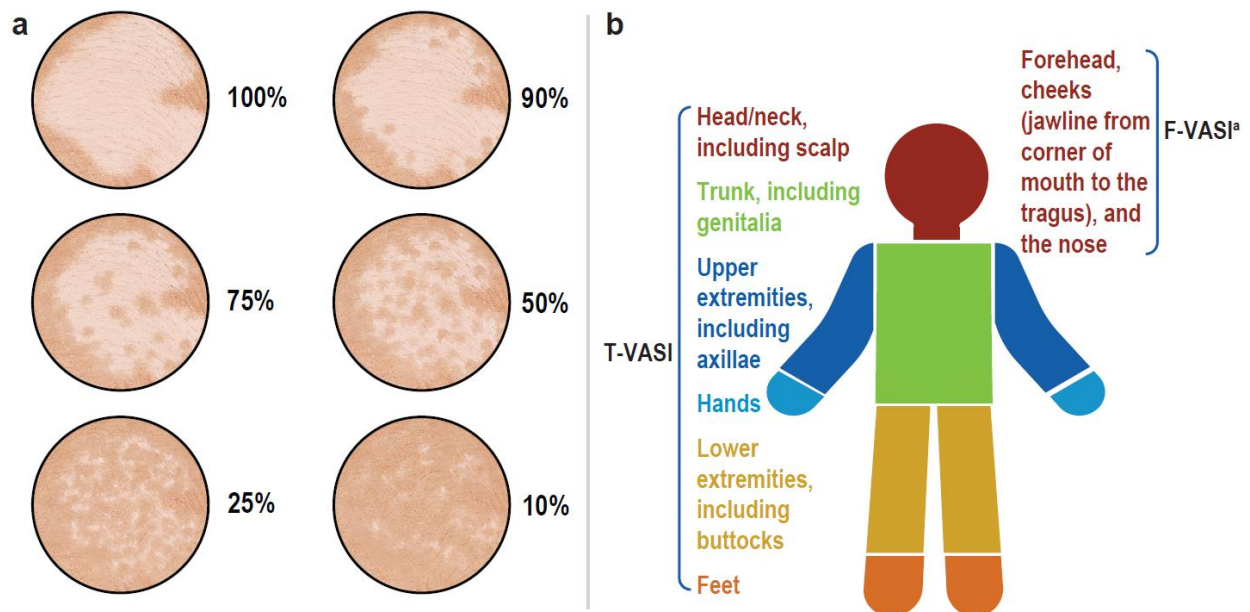
Supplementary Material Table 1. PhGVA and PaGIC-V Scales

PhGVA		PaGIC-V	
Score (severity)	Description	Score	Description; change from baseline visit
0 (Clear)	No signs of vitiligo or complete/near complete repigmentation	1	Very much improved
1 (Almost clear)	Mostly pigmented areas with small depigmented or difficult to repigment areas (eg, philtrum, nares, corners of eyes, perioral skin)	2	Much improved
2 (Mild disease)	Modest areas of depigmentation (not more than half of facial skin) with approximately 50% pigmentation within vitiligo areas or significant perifollicular pattern present	3	Minimally improved
3 (Moderate disease)	Large areas of depigmented vitiligo areas (>50% of facial skin); significant depigmentation within vitiligo areas	4	No change
4 (Severe disease)	Extensive areas of vitiligo to complete depigmentation on face	5	Minimally worse
		6	Much worse
		7	Very much worse

PaGIC-V, Patient Global Impression of Change–Vitiligo; PhGVA, Physician’s Global Vitiligo Assessment.

Supplementary Material Figure 1. Determination of F-VASI and T-VASI Scores Based on

(a) Degree of Depigmentation and (b) Anatomic Regions for T-VASI

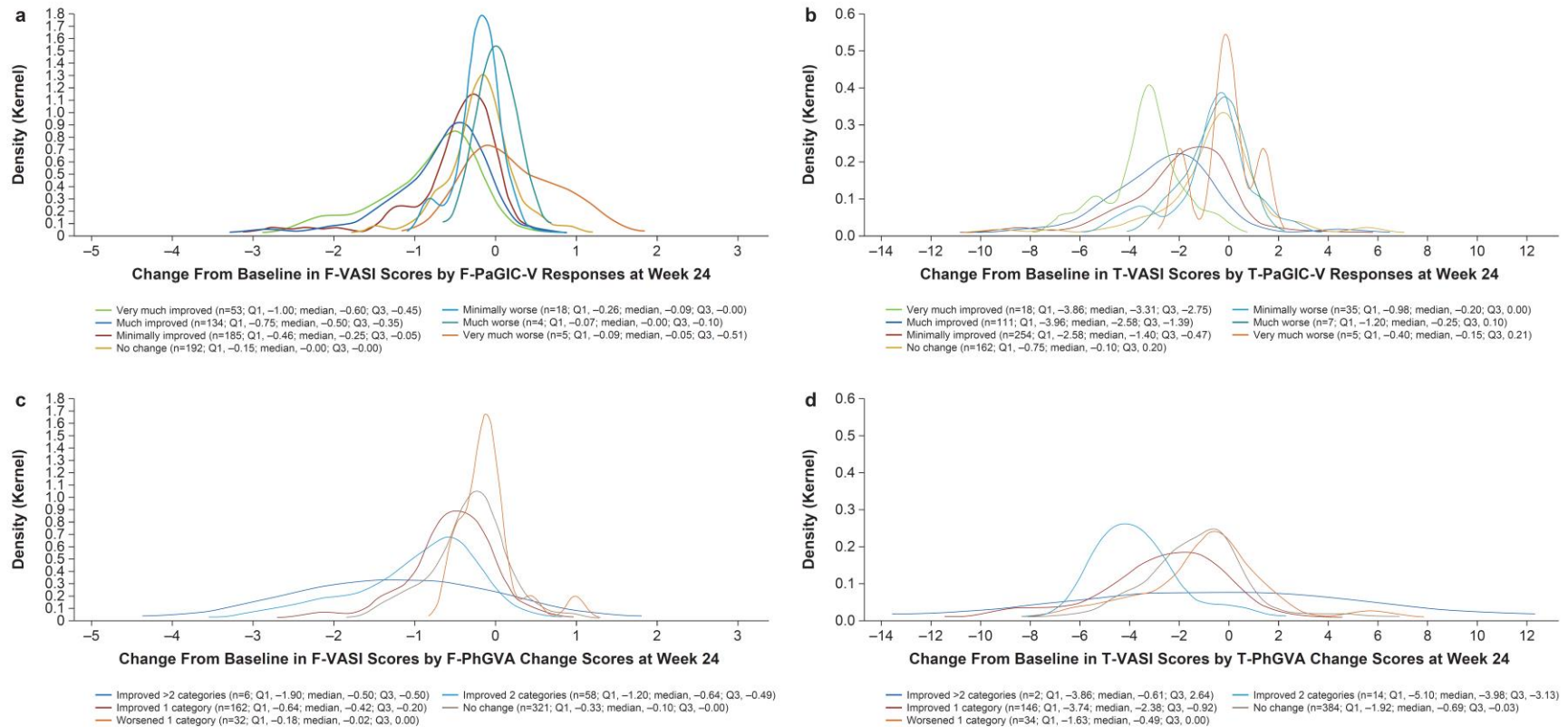


F-VASI, facial Vitiligo Area Scoring Index; T-VASI, total Vitiligo Area Scoring Index.

^a For F-VASI, the face was defined as including the forehead to the original hairline, the cheeks to the jawline vertically and laterally from the corner of the mouth to the tragus, nose, and eyelids; the surface area of the lips, scalp, ears, and neck were excluded.

For T-VASI, the body was divided into 6 separate and mutually exclusive sites: head/neck, hands, upper extremities (excluding hands), trunk, lower extremities (excluding feet), and feet.

Supplementary Material Figure 2. Probability Density Function for (a) F-VASI Scores and (b) T-VASI Scores by PaGIC-V Responses at Week 24, and (c) F-VASI Scores and (d) T-VASI Scores by PhGVA Change Scores at Week 24



FAS, full analysis set; F-PaGIC-V/T-PaGIC-V, facial/total Patient Global Impression of Change–Vitiligo; F-PhGVA/T-PhGVA, facial/total Physician’s Global Vitiligo Assessment; F-VASI, facial Vitiligo Area Scoring Index; T-VASI, total Vitiligo Area Scoring Index.