

Supplemental Online Content

Ezzedine K, Soliman AM, Camp HS, et al. Psychometric Properties and Meaningful Change Thresholds of the Vitiligo Area Scoring Index. *JAMA Dermatol*. Published online October 30, 2024. doi:10.1001/jamadermatol.2024.4534

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This supplemental material has been provided by the authors to give readers additional information about their work.

eMethods. Key Selection Criteria for the Phase 2 Trial

- Inclusion criteria:
 - Clinical diagnosis of nonsegmental vitiligo (NSV) and no segmental or localized vitiligo.
 - Participants with all of the following at Screening and Baseline:
 - Visits: ≥ 0.5 Facial-Vitiligo Area Scoring Index (F-VASI) and ≥ 5 total-Vitiligo Area Scoring Index (T-VASI).
 - Participants who have had prior exposure to immunomodulatory biologic therapy, for any indications, but discontinued the biologic therapy prior to the first dose of study drug. Recommended washout periods for biologic therapies include ≥ 4 weeks for etanercept; ≥ 8 weeks for adalimumab, infliximab, certolizumab, golimumab, abatacept, tocilizumab, and ixekizumab; ≥ 16 weeks for secukinumab; and ≥ 12 weeks for ustekinumab. For biologic therapies not specified, therapies must be discontinued at least five times the mean terminal elimination half-life of a drug or 3 months prior to Baseline, whichever is longer.
- Exclusion criteria:
 - Participants with segmental or localized vitiligo.
 - Participants with other skin conditions that would interfere with evaluation of vitiligo, participants with uncontrolled thyroid disease, and participants with $>33\%$ leukotrichia on the face or $>33\%$ leukotrichia on the body (including face).
 - Participants previously treated with any topical or systemic janus kinase (JAK) inhibitor or permanent skin bleaching agents.
 - Participants treated with any systemic vitiligo therapy (e.g., methotrexate, mycophenolate mofetil, corticosteroids), supplemental vitiligo therapy (antioxidants/vitamins/herbal medicine/traditional Chinese medicine), and/or topical vitiligo therapy including permanent or temporary tattoos within a minimum of 30 days prior to the first dose of study drug (Note: Camouflage and makeup may be used).
 - Participants treated with any phototherapy, including excimer (or other forms of laser therapy), within a minimum of 12 weeks prior to the first dose of study drug.
 - Participants have history of malignancy other than successfully treated non-melanoma skin cancer (NMSC) or localized carcinoma in situ of the cervix.
 - Recent (within past 6 months) cerebrovascular accident, myocardial infarction, coronary stenting, and aorto-coronary bypass surgery.
 - History of an organ transplant which requires continued immunosuppression.
 - History of gastrointestinal perforation (other than due to appendicitis or mechanical injury), diverticulitis, or significantly increased risk for gastrointestinal perforation per investigator judgment.
 - Conditions that could interfere with drug absorption including but not limited to short bowel syndrome or gastric bypass surgery; subjects with a history of gastric banding/segmentation are not excluded.
 - Uncontrolled thyroid disease.

eTable 1. Sites Recruiting Participants for Embedded Interviews

Site	Location
Dawes Fretzin Dermatology Group	Indianapolis, IN
Virginia Clinical Research, Inc.	Norfolk, VA
Michigan Center for Research	Clarkston, MI
Essential Medical Research	Tulsa, OK
Remington-Davis Clinical Research	Columbus, OH
Oregon Dermatology and Research Center	Portland, OR

eTable 2. Interviewers

Interviewer Name	Degree	Job Title	Sex	Relationship to Participants
Rodolfo Matos	MAA	Research Associate, Patient Centered Research, Evidera	Male	None
Mary Kate Ladd	MA	Senior Research Associate, Patient Centered Research, Evidera	Female	None
Hope Paul	MS, RD, CDCES	Manager, Scientific Education and Training, Patient Centered Research, Evidera	Female	None

eTable 3. Additional Patient- and Physician-reported Outcomes for Assessing Vitiligo

Outcome measure	Assessment	Possible responses
Vitiligo Noticeability Scale (VNS)	Patients are asked, “Compared to before treatment, how noticeable is the vitiligo now?”	5-point scale from 1 (more noticeable) to 5 (no longer noticeable)
Face-Patient Global Vitiligo Assessment (F-PaGVA)	Patients are asked, “Please choose the response below that best describes the extent of the vitiligo on your face today.”	5-point scale ranging from 0 (no depigmentation) to 4 (very extensive depigmentation)
Total-Patient Global Vitiligo Assessment (T-PaGVA)	Patients are asked, “Please choose the response below that best describes the extent of the vitiligo over your entire body today.”	5-point scale ranging from 1 (much better) to 5 (much worse)
Patient’s Global Impression of Change-Vitiligo (PaGIC-V)	Patients are asked, “Please choose the response below that best describes the extent of the vitiligo on your face today.”	5-point scale ranging from 1 (no depigmentation) to 5 (very extensive depigmentation)
Face-Physician Global Vitiligo Assessment (F-PhGVA)	Physicians are asked to quantify the severity of the patient’s vitiligo across on the face	5-point scale ranging from 0 (no depigmentation) to 4 (very extensive depigmentation)
Total-Physician Global Vitiligo Assessment (T-PhGVA)	Physicians are asked to quantify the severity of the patient’s vitiligo across the body	5-point scale ranging from 0 (no depigmentation) to 4 (very extensive depigmentation)

eTable 4. Reproducibility and Test-retest Reliability of the T-VASI and F-VASI

Analysis	N	Screening	Mean (SD)		Paired <i>t</i> test		Spearman correlation		ICC (95% CI)
			Baseline	Difference	<i>t</i> -value	<i>P</i> -value	Coefficient	<i>P</i> -value	
Reproducibility: screening vs. baseline									
T-VASI	162	21.4 (16.7)	21.7 (16.9)	0.26	-0.95	0.34	0.99	<0.0001	0.98 (0.97–0.98)
F-VASI	162	1.1 (0.6)	1.1 (0.6)	0.02	-1.59	0.11	0.92	<0.0001	0.95 (0.94–0.96)
Test-retest reliability in clinically stable participants from baseline to week 4 ^a									
T-VASI	115	22.1 (17.4)	21.7 (17.4)	-0.39	1.38	0.17	0.98	<0.0001	0.99 (0.98–0.99)
F-VASI	124	1.1 (0.6)	1.05 (0.7)	-0.02	1.94	0.054	0.97	<0.0001	0.98 (0.98–0.99)

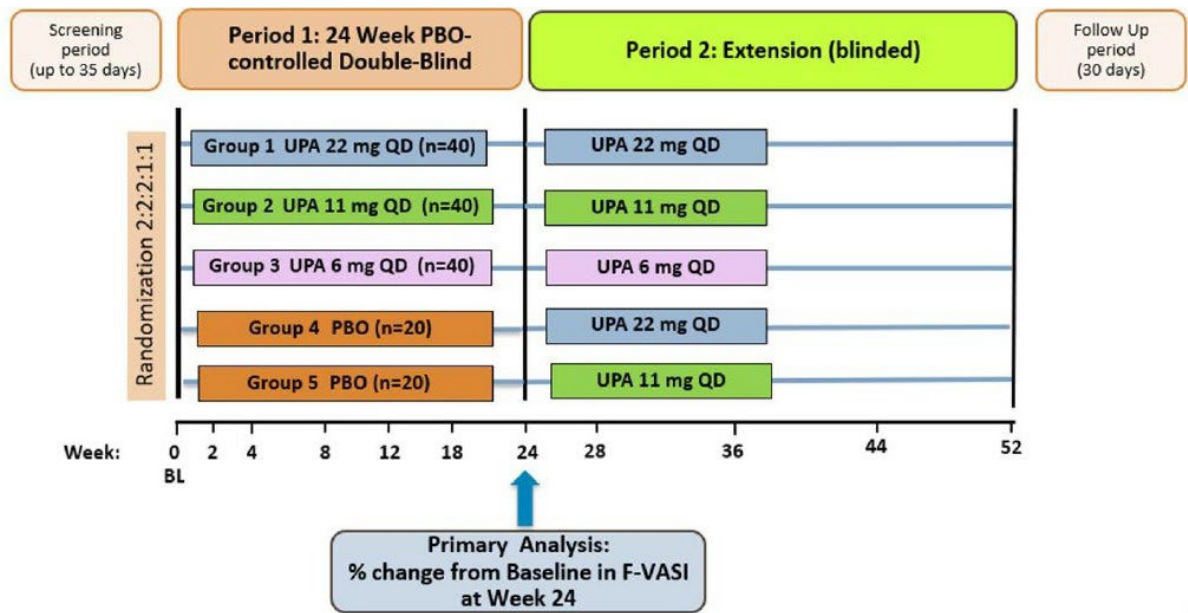
Abbreviations: CI, confidence interval; F-VASI, Facial-Vitiligo Area Scoring Index; ICC, intraclass correlation coefficient; SD, standard deviation; T-VASI, Total-Vitiligo Area Scoring Index.

^aThe clinically stable population was defined as participants with no change in response on the Face-Physician's Global Vitiligo Assessment (for F-VASI) and Total-Physician's Global Vitiligo Assessment (for T-VASI) during the time of interest (baseline to week 4).

eTable 5. Patient Characteristics

Characteristic	Psychometric analysis N=164	Embedded interviews N=14
Age (y), mean (SD) [range]	46.0 (11.2) [18-66]	48.8 (12.2) [25-65]
Sex, n (%)		
Male	61 (37.2)	5 (35.7)
Female	103 (62.8)	9 (64.3)
Ethnicity, n (%)		
Hispanic or Latino	16 (9.8)	1 (7.1)
Not Hispanic or Latino	148 (90.2)	13 (92.9)
Race, n (%)		
American Indian/Alaskan Native	1 (0.6)	0 (0.0)
Asian	23 (14.0)	0 (0.0)
Black or African American	11 (6.7)	1 (7.1)
Native Hawaiian/Pacific Islander	1 (0.6)	0 (0.0)
White	113 (68.9)	12 (85.7)
Multiple or other	4 (2.4)	1 (7.1)
Missing	11 (6.7)	0 (0.0)

Abbreviation: SD, standard deviation



eFigure 1. Schematic of the Phase 2 Clinical Trial

Abbreviations: BL, baseline; F-VASI, Facial Vitiligo Area Scoring Index; PBO, placebo; QD, once daily; UPA, upadacitinib.

Total and Facial Vitiligo Assessment Scoring Index (T-VASI and F-VASI)

Subject number	
Visit	
Date	

VASI

$$= \sum_{\text{All Body Sites}} [\text{Hand Units}] \times [\text{Residual Depigmentation}]$$



Hand Unit: 1
Thumb unit: 0.1

- Of note, one hand unit is the equivalent to 1% BSA. For column A, enter HAND OR THUMB UNIT (numerical number).

T-VASI

		A	B	C
	Max BSA reference (%)	Enter BSA <u>in hand unit</u> 1 Hand Unit = 1% BSA 1 Thumb Unit = 0.1 Hand Unit = 0.1 % BSA	Residual Depigmentation Rate 0/.1/.25/.5/.75/.9/1.0*	Regional VASI = [column A] X [column B]
Head/neck	9			
Upper Extremities (+ axillae) (- hands)	14			
Hands	4			
Trunk (+ genitalia)	33			
Lower Extremities (+ buttocks) (- feet)	36			
Feet	4			
Total VASI Score				

* Assess residual depigmentation to the nearest of the following %: 0, 10, 50, 25, 75, 90, or 100%



≥ 5 T-VASI at Screening and Baseline is required

- Complete Column A, B, and C for body areas and enter this information into the electronic data capture (EDC).
- EDC will automatically calculate Total VASI Score in Column C (yellow highlighted box) once you submit the Total VASI eCRF. Make sure to re-open the Total VASI eCRF to review and confirm the calculation.

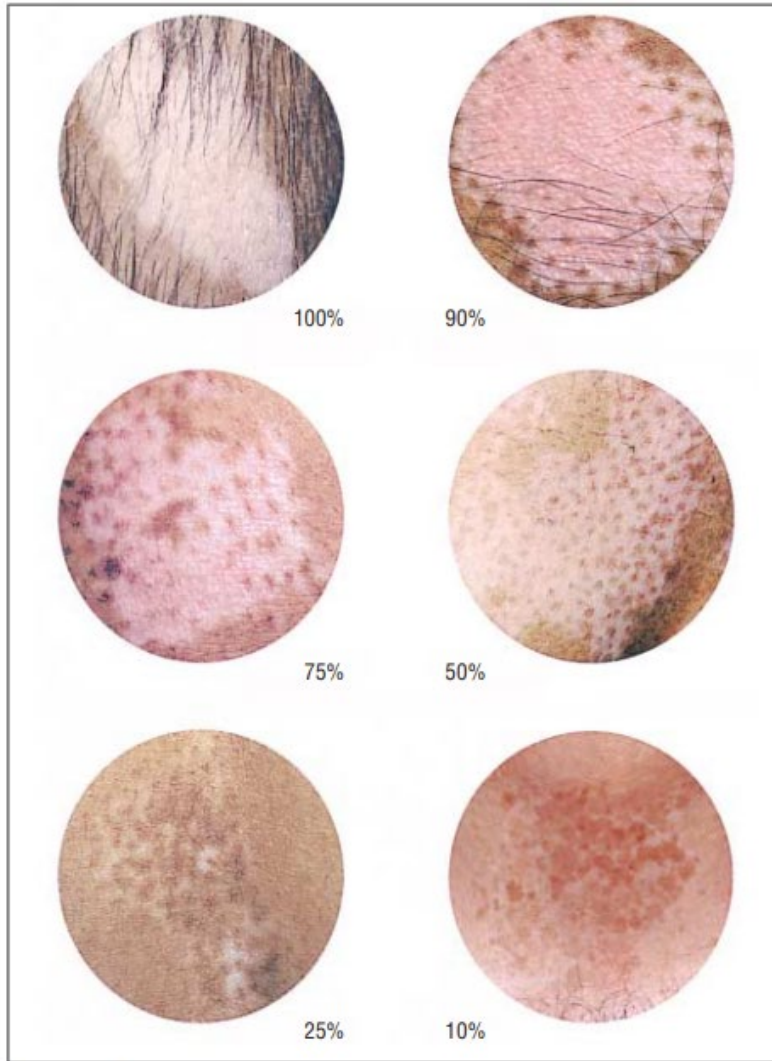



Figure 1. Standardized assessments for estimating the degree of pigmentation to derive the Vitiligo Area Scoring Index. At 100% depigmentation, no pigment is present; at 90%, specks of pigment are present; at 75%, the depigmented area exceeds the pigmented area; at 50%, the depigmented and pigmented areas are equal; at 25%, the pigmented area exceeds the depigmented area; and at 10%, only specks of depigmentation are present.

Facial Vitiligo Assessment Scoring Index (F-VASI)

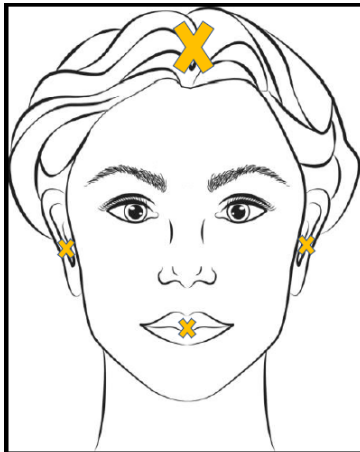
Subject number	
Visit	
Date	

F-VASI

	A	B	C
Face: exclude the lips, ears and scalp	Enter Facial BSA in Hand Unit (Max = 3 % BSA) 1 Hand Unit = 1% BSA 1 Thumb Unit = 0.1 Hand Unit = 0.1 % BSA	Residual Depigmentation Rate 0/.1/.25/.5/.75/.9/1.0*	F-VASI = [column A] X [column B]

* Assess residual depigmentation to the nearest of the following %: 0, 10, 25, 50, 75, 90, or 100% 

≥ 0.5 F-VASI at Screening and Baseline is required



Note: For the F-VASI measurement, include all areas of the face except the lips, ears, and scalp.

- Complete Columns A and B for Face and enter this information into the electronic data capture (EDC).
- EDC will automatically calculate Facial VASI Score in Column C (yellow highlighted box). once you submit the Facial VASI eCRF. Make sure to re-open the Facial VASI eCRF to review and confirm the calculation.

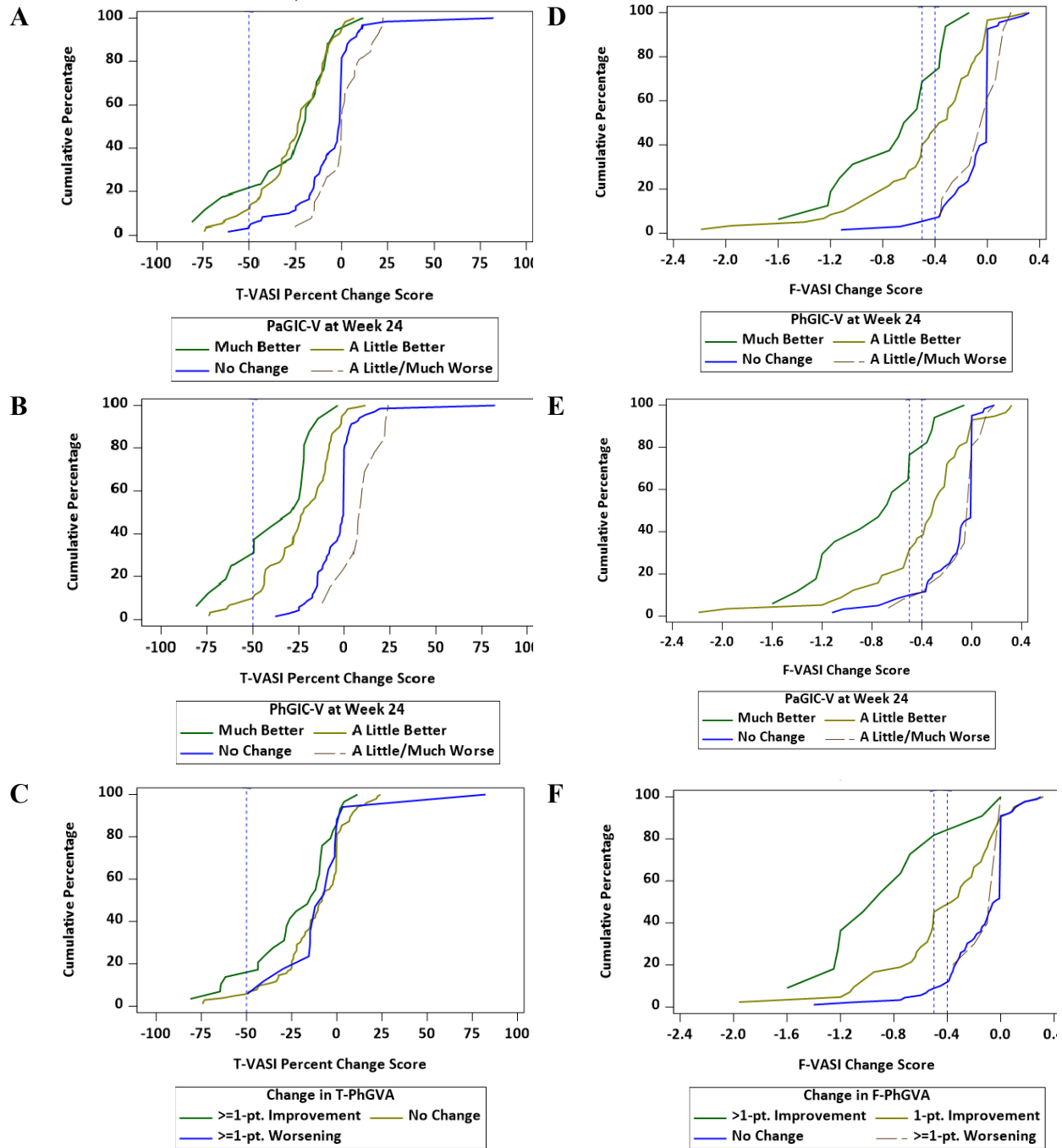
Investigator _____

Signature _____

Date _____

eFigure 2. T-VASI and F-VASI Scoring Sheet

Abbreviations: BSA, body surface area; EDC, electronic data capture; F-VASI, Facial-Vitiligo Area Scoring Index; T-VASI, Total-Vitiligo Area Scoring Index



eFigure 3. Empirical Cumulative Distribution Function Curves for T-VASI (A-C) and F-VASI (D-F) Across Response Levels

Abbreviations: F-PhGVA, Face-Physician Global Vitiligo; F-VASI, Facial-Vitiligo Area Scoring Index; PaGIC-V, Patient’s Global Impression of Change-Vitiligo; PhGIC-V, Physician’s Global Impression of Change-Vitiligo; T- PhGVA, Total-Physician Global Vitiligo Assessment; T-VASI, Total-Vitiligo Area Scoring Index.

eAppendix. Semi-structured Interview Guide

It is important to note that this document is to be used as a guide only. The actual areas of conversation are fluid and may be discussed at moments different from the order appearing below. The interview will take no more than 60 minutes with breaks as needed. The interviewer may adapt the guide so topics are covered in the amount of time allotted for the session or to best elicit responses from the participants.

Probes included in this script will be used to guide the discussion if the participant seems confused or is unable to provide a response without assistance. Additional unscripted probes to be used to gain further information or clarification may include:

Clarification: Could you please explain this to me in more detail?

Expressing understanding: How do/how would you cope with that?

Justification: What makes you say that?

Importance: Could you go into a bit more detail on this and give me more background on why they are important?

Extending narrative: Tell me a bit more about that.

Accuracy: Let's see if I've got that right.

Note to Interviewer:

Italic Text: Instructions to the interviewer, should not be read to the participant

INTRODUCTION

I would like to verify, did you sign the informed consent form to participate in this study at the clinic site or online via DocuSign? ***If no, discontinue and follow up with the site.***

Thank you for agreeing to speak with me today. My name is [X], and I am [XXXX] at Evidera, a research consulting group. You were invited to take part in our study because you have vitiligo and are participating in AbbVie's clinical trial. Today I will ask you questions about your experience with vitiligo and in this clinical trial.

I want to remind you that you are a volunteer. This means that you can skip any question you don't want to answer, and you can stop the interview at any time. Also, all of your responses will be confidential as detailed in the consent form. The study report and summary information about this interview study will not be linked to your identity.

I am not a doctor or nurse, so if you have any medical questions that come up because of our discussion today, please ask your healthcare provider. I would like to ask you if it's OK to audio record this interview. Your name will not be linked with your responses in any way. The recording will be used to help us write a report about the things we talked about here today. The report also will include information that we get from other patients that were in this study.

Do you have any questions before we begin?

Answer any questions

After participant signs the consent form: Begin Recorder: This is study EVA-31203, this is [Participant ID] and today's date is [insert date]. I want to confirm that you did read and sign a consent form? ***Wait for verbal affirmation.***
Is it ok for me to audio record this interview? ***Wait for verbal affirmation***

Part I. Brief Introduction

I want to start by asking you a few general questions about your vitiligo. First, how do you refer to your vitiligo? What do you call it? [*interviewer, use their phrasing throughout the interview*]

- When did you first notice your vitiligo? How old were you and how long ago was that?
 - What body area?
 - What first led you to consult a doctor?
 - How much time went by before you asked a clinician about your symptoms?
 - A white spot.
 - Has the area of your body that is impacted by vitiligo changed over time? How quickly? Please walk me through the changes (number of areas, area location, size of area depigmented, severity of depigmentation). [*interviewer, use the phrasing the participant uses throughout the interview, depigmentation/repigmentation*]
- What led you to participate in this clinical trial?
 - Have you had treatment for vitiligo in the past? If yes, in what ways was that treatment helpful? In what ways did the treatment not meet your expectations?

Part II. Skin depigmentation

Thank you for providing that background information. Now I would like to discuss your vitiligo condition a little more thoroughly.

- Prior to the trial, what bothered you the most about your vitiligo?

*Assuming depigmentation, for each body area mentioned by the participant, **probe** as follows:*

- Area of the body-location, size, severity, and noticeability of impacted areas
 - What does noticeability mean to you?
 - Probe: noticeable to you, your family, others in public, ability to cover up noticeable depigmentation
- How would you describe how bad or severe the vitiligo areas were?
- If the areas listed below are not spontaneously mentioned by the participant, probe for vitiligo symptoms in each of these body areas (listed below) Probe about depigmentation and information about size, severity, and noticeability:
 - Face/Head
 - Scalp, lips/around lips, ears, forehead/above eyebrows, around eyes, cheeks, jawline/chin
 - Neck
 - Arms
 - Hands
 - Trunk/torso (chest, stomach, back, genitalia)
 - Legs
 - Feet

Have you had any other vitiligo symptoms, other than skin depigmentation?

For each sign or symptom, ask whether and how it has changed since starting study medication.

If the following symptoms are not spontaneously named, probe for the following signs and symptoms:

- Patches or skin lesions
 - Where, which areas are most bothersome?
- Loss of hair color
- Skin sensitivity to the sun
- Skin itching, tingling, crawling or burning
 - Where, which areas are most bothersome?

Part III: Vitiligo Impacts

Thank you for discussing your vitiligo with me. Now I'd like to take some time to hear how vitiligo has impacted your life.

Prior to the trial, how did your vitiligo impact your daily life? What role did vitiligo play in your day to day?

- Did the number of areas of depigmentation play a role in the impact on your life? How so?
- Did the location of depigmentation play a role in the impact on your life? How so?
- Did the size of the area of depigmentation play a role in the impact on your life? How so?
- Did the severity of depigmentation play a role in the impact on your life? How so?
- Did the noticeability of depigmentation play a role in the impact on your life? How so?

If not named, probe the below and assess if there is an impact relationship between location/amount of depigmentation:

- Social impact (e.g. isolation, avoiding activities, bullying, relationship impact/avoidance of intimacy, lack of understanding from others, social phobia or anxiety)
 - Impact on sexuality/intimacy (e.g. avoidance of intimacy, avoidance of sex, sexual dysfunction/difficulties, difficulty showing affection)
- Psychosocial impact (e.g. self-esteem/confidence, disempowerment, worry, shame, depression, anxiety, anger, self-consciousness, embarrassment, disappointment, fear, frustration, discouragement, feeling unattractive)
- Work/School impact (e.g. career choice, education choice, ability to get employment, discrimination)
- Sleep impact (e.g. sleep disturbances, fatigue)
- Impact on daily activities (desire to hide/disguise vitiligo[e.g., the use of makeup/choice of clothing], avoidance of activities with sun exposure, avoidance of activities with skin exposure)
- Impact on leisure activities (e.g. avoidance of social/leisure activities, avoidance of sports/hobbies with skin exposure, avoidance of sports/hobbies with sun exposure)

Part IV. Clinical Trial Expectations and Change Hopes Prior to the Clinical Trial

Now I would like to ask you about your expectations of the clinical trial and if you experienced changes in your vitiligo during the trial.

- **Before** the trial began, what were your expectations?
 - What did you hope would change during the trial?
 - Probe: number of areas, location of body, size of area of depigmentation, severity of depigmentation, noticeability of depigmentation
 - What areas of your body did you hope to see change?
 - Where?
 - By how much area?
 - By how much depigmentation /shade?
 - Based on what you just described, would those physical changes be meaningful to you?
 - What changes were you hoping the depigmentation would have on your daily life?
 - Probe for expectations in: Social impacts, Impact on sexuality/intimacy, Psychosocial impacts, Work, Sleep impact, Impact on daily activities, Impact on leisure activities
 - Based on what you just described, would those daily life changes be meaningful to you?

MEANINGFUL CHANGE SERIES OF THE INTERVIEW

Interviewer Note: Use the below sections and probes to answer the following key questions:

1. *Did the participant notice changes in their vitiligo during the trial?*
2. *What changes were noticed, was the change an improvement or deterioration?*
3. *How meaningful was the change and why?*

The interviewer should take notes so to make efficient probes; a notes table may be used by the interviewer, such as:

Sign/Symptom/Impact	Improvement/Deterioration	Meaningful? Yes/No	How so?
Part V Interview Questions		Part VI Interview Questions	

Part V. Changes During to the Clinical Trial and at the End of the Clinical Trial

- At the end of the clinical trial, did you experience any changes in your vitiligo compared to before the trial?
Interviewer note these could be improvements or worsening
 - If yes ...
 - What specific change did you notice?
 - Probe: number of areas, location of body, size of area of depigmentation, severity of depigmentation, noticeability of depigmentation
 - *Interviewer note you may need to repeat probes for each area of the body*
 - Was your vitiligo less severe or more severe?
 - Was your vitiligo less bothersome or more bothersome? *Probe: Why?*
 - When during the clinical trial did you first notice the change? (e.g., after the first treatment dosage, after several weeks)
 - Where on your body did you first notice the change?
 - Did the change stay consistent during the trial?
- At the end of the clinical trial, did you experience any changes in how vitiligo impacts your life trial compared to before the trial?
 - Did you experience any change in the impacts of vitiligo?
 - Did the impact of vitiligo on your daily life change?
 - Probe on areas of impact from Part III above (social, psychosocial, work/school, sleep, daily activities, leisure activities, sexuality)

Part VI. Perspectives about Meaningful Change at the end of the Clinical Trial

I've asked you about your vitiligo before, during, and after the clinical trial. Now I'm going to ask you about meaningful change.

- I would like to know, overall, would you say the trial treatment resulted in a meaningful change for you? What makes you say that?
 - *Interviewer Probe for meaningful improvement or meaningful deterioration*
 - **Signs/Symptoms** Was the change in your vitiligo that you experienced as a result of the trial meaningful to you? (*Interviewer, other ways to ask about 'meaningful change' Did the change matter?*)
 - In what ways was the change meaningful?
 - Probe: number of areas, location of body, size of area of depigmentation, severity of depigmentation

- *Interviewer note you may need to repeat probes for each area of the body*
- **Impacts/Daily Life** Thinking about changes in the way vitiligo impacts your daily life, would you say the trial treatment resulted in a meaningful change for you? (*Interviewer, other ways to ask about ‘meaningful change’ Did the change matter?*)
 - What makes you say that it was/was not a meaningful change?
 - Probe on areas of impact from Part III above (social, psychosocial, work/school, sleep, daily activities, leisure activities, sexuality)

[For patients who say the change was not meaningful]

- What changes in your vitiligo would have been meaningful? *Assuming the answer is regarding skin pigmentation...*
 - Probe *Interviewer note you may need to repeat probes for each area of the body and the responses may be layered (e.g., percent re-pigmentation that is meaningful for some areas but not others):*
 - number of areas
 - location of vitiligo on body, are some areas more important than others when thinking about meaningful treatment benefit? What areas and why?
 - size of area of depigmentation
 - severity of depigmentation: Ask: What is the minimum level of repigmentation (regaining of pigment) that would be meaningful to you?, Ask 25% re-pigmentation (would it be meaningful if you regained a quarter of your pigment?), 50% (would it be meaningful to you if you regained half your pigment?), 75% (would it be meaningful to you if you regained three quarters of your pigment?), 90%, 100%. Would the percent repigmentation be different on different parts of your body?
 - Are there other aspects of your vitiligo that would need to be improved for you to consider a treatment benefit to be meaningful?

Overall, thinking about your vitiligo since the beginning of the trial, 6 months ago [*interviewer to state the month it would have been 6 months ago*], did the treatment provide a meaningful benefit?

- Yes Please explain
- No Please explain

Part VII. Meaningful Change on Questionnaires

For the next part of the interview, I am going to ask you some questions based on questionnaires that are commonly used to evaluate vitiligo.

Vitiligo Area Scoring Index

- I am going to list (or show if web-based interview) areas of the body. Please tell me what areas are more important to you to have re-pigmentation than others? Please rank these from most important to least important to you.
 - Face
 - Head/neck
 - Arms
 - Hands
 - Trunk/torso (chest, stomach, back, genitalia)
 - Legs
 - Feet
- What amount of re-pigmentation marks a meaningful improvement? (100% is total lack of depigmentation)
 - Does the amount of a meaningful improvement change based on area of the body? If so what percent for each area? (e.g., Are there certain areas of the body where it would be

more important to have 100% re-pigmentation than others? How about areas where it would be less important?)

Vitiligo Noticeability Scale

Show the VNS on the screen if web-based interview.

I'm going to ask you questions about the answer choices you see in the screen. Let's work from the bottom up. Please think about your vitiligo and describe what you would experience. You may consider the number of areas, area location, size of area, severity of depigmentation, and noticeability of depigmentation.

- In your own words, can you tell me what "No longer noticeable" means to you?
- In your own words, can you tell me what "A lot less noticeable" means to you?
- In your own words, can you tell me what "Slightly less noticeable" means to you?
- In your own words, can you tell me what "As noticeable" means to you?
- In your own words, can you tell me what "More noticeable" means to you?
- *Probe number of areas, area location, size of area, severity, and noticeability*

I would like to know which answer would mean that you benefited from treatment. For example, if you were in a clinical trial and at the end picked:

- "No longer noticeable" would that be a meaningful improvement, why? *(Interviewer to use phrase participant is comfortable with such as treatment benefit, successful treatment, meaningful change that is positive)*
- "A lot less noticeable" would that be a meaningful improvement, why? *(Interviewer to use phrase participant is comfortable with such as treatment benefit, successful treatment, meaningful change that is positive)*
- "Slightly less noticeable" would that be a meaningful improvement, why? *(Interviewer to use phrase participant is comfortable with such as treatment benefit, successful treatment, meaningful change that is positive)*
- "As noticeable" would that be a meaningful improvement, why? *(Interviewer to use phrase participant is comfortable with such as treatment benefit, successful treatment, meaningful change that is positive)*
- "More noticeable" would that be a meaningful improvement, why? *(Interviewer to use phrase participant is comfortable with such as treatment benefit, successful treatment, meaningful change that is positive)*

Patient's Global Impression of Change- Vitiligo

Show the PaGIC-V on the screen if web-based interview.

I'm going to ask you questions about these answer choices you see in the screen.

Let's work from the top to the bottom this time. Please think about your vitiligo and describe what you would experience. You may consider the number of areas, area location, size of area, severity of depigmentation, and noticeability of depigmentation.

- In your own words, can you tell me what "Much better" means to you?
- In your own words, can you tell me what "A little better" means to you?
- In your own words, can you tell me what "No change" means to you?
- In your own words, can you tell me what "A little worse" means to you?
- In your own words, can you tell me what "Much worse" means to you?
- *Probe number of areas, area location, size of area, severity, and noticeability*

I would like to know which answer would mean that you benefited from treatment. For example, if you were in a clinical trial and at the end picked:

- "Much better" would that be a meaningful improvement, why? *(Interviewer to use phrase participant is comfortable with such as treatment benefit, successful treatment, meaningful change that is positive)*
- "A little better" would that be a meaningful improvement, why? *(Interviewer to use phrase participant is comfortable with such as treatment benefit, successful treatment, meaningful change that is positive)*
- "No change" would that be a meaningful improvement, why? *(Interviewer to use phrase participant is comfortable with such as treatment benefit, successful treatment, meaningful change that is positive)*
- "A little worse" would that be a meaningful improvement, why? *(Interviewer to use phrase participant is comfortable with such as treatment benefit, successful treatment, meaningful change that is positive)*

- “Much worse” would that be a meaningful improvement, why? (*Interviewer to use phrase participant is comfortable with such as treatment benefit, successful treatment, meaningful change that is positive*)

Total- Patient’s Global Vitiligo Assessment

Show the T-PaGVA on the screen if web-based interview.

Again, I’m going to ask you questions about the answer choices you see in the screen. Let’s work from the top to the bottom. Please think about your vitiligo and describe what you would experience. You may consider the number of areas, area location, size of area, severity of depigmentation, and noticeability of depigmentation.

- In your own words, can you tell me what “No depigmentation” means to you?
- In your own words, can you tell me what “Limited extent of depigmentation” means to you?
- In your own words, can you tell me what “Moderate extent of depigmentation” means to you?
- In your own words, can you tell me what “Extensive depigmentation” means to you?
- In your own words, can you tell me what “Very extensive depigmentation” means to you?
- *Probe number of areas, area location, size of area, severity, and noticeability*

In a clinical trial patients would answer this question at the start and at the end. I’m wondering for you, what change would constitute an improvement. Let’s look at the choices together

- If you went from Very extensive depigmentation to Extensive depigmentation, would that be a benefit? [4-3]
 - If yes, Why?
 - If no, probe from Very extensive depigmentation to what level would be meaningful? (moderate extent of depigmentation; limited extent of depigmentation; no depigmentation)
- If you went from Extensive depigmentation to Moderate extent of depigmentation, would that be a benefit? [3-2]
 - If yes, Why?
 - If no, probe from Extensive depigmentation to what level would be meaningful? (limited extent of depigmentation; no depigmentation)
- If you went from Moderate extent of depigmentation to Limited extent of depigmentation, would that be a benefit? [2-1]
 - If yes, Why?
 - If no, probe from Moderate extent of depigmentation to what level would be meaningful? (no depigmentation)
- If you went from Limited extent of depigmentation to No depigmentation, would that be a benefit? [1-0]
 - If yes, Why?
 - If no, probe about meaningful change if you started at Limited extent of depigmentation

Face- Patient’s Global Vitiligo Assessment

Show the F-PaGVA on the screen if web-based interview.

This question is similar but it is for only the Face. I’m going to ask you questions about the answer choices you see in the screen. Let’s work from the top to the bottom. Please think about your vitiligo and describe what you would experience. You may consider the number of areas, area location on the face, size of area, severity of depigmentation, and noticeability of depigmentation.

- In your own words, can you tell me what “No depigmentation” means to you?
- In your own words, can you tell me what “Limited extent of depigmentation” means to you?
- In your own words, can you tell me what “Moderate extent of depigmentation” means to you?
- In your own words, can you tell me what “Extensive depigmentation” means to you?
- In your own words, can you tell me what “Very extensive depigmentation” means to you?
- *Probe number of areas, area location, size of area, severity, and noticeability*

In a clinical trial patients would answer this question at the start and at the end. I'm wondering for you, what change would be a benefit and why. Let's look at the choices together

- If you went from Very extensive depigmentation to Extensive depigmentation, would that be a benefit? [4-3]
 - If yes, Why?
 - If no, probe from Very extensive depigmentation to what level would be meaningful? (moderate extent of depigmentation; limited extent of depigmentation; no depigmentation)
- If you went from Extensive depigmentation to Moderate extent of depigmentation, would that be a benefit? [3-2]
 - If yes, Why?
 - If no, probe from Extensive depigmentation to what level would be meaningful? (limited extent of depigmentation; no depigmentation)
- If you went from Moderate extent of depigmentation to Limited extent of depigmentation, would that be a benefit? [2-1]
 - If yes, Why?
 - If no, probe from Moderate extent of depigmentation to what level would be meaningful? (no depigmentation)
- If you went from Limited extent of depigmentation to No depigmentation, would that be a benefit? [1-0]
 - If yes, Why?
 - If no, probe about meaningful change if you started at Limited extent of depigmentation

Part VII. Conclusion

Thank you very much for your help, we have now completed the interview. ***Inform the participant that payment will be uploaded to the payment card.***