EVM-25004 Patient Interview Guide Instructions and Questions

Note: *Below is a semi-structured script. It 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 be approximately 60-90 minutes with breaks as needed. The interviewer may adapt the guide in order to cover the topics in the amount of time allotted for the session or in order to best elicit concepts from the participants.*

Interviewer is responsible for pre-populating dates throughout interview guide and the scores in the PRO Data section.

Prior to the start of the discussion, please check that:

Patient has been deemed eligible.	☐ Yes	☐ No
Patient has consented prior to the discussion.	☐ Yes	☐ No

Introduction

Thank you for agreeing to take part in this interview. Before we get started:

When did you first enroll in the trial? _____ *(enter date)*

[Interviewer: have date available for confirmation if patient cannot come up with exact date]

Are you still in the study, or did you withdraw early?

If the patient stopped the study prematurely, please STOP the interview.

Number of visits completed: _____ *(enter number of visits)*

If the patient has not completed the week 16 visit, please STOP the interview.

As you read in the consent form at the beginning of the clinical trial, this session will be audio-recorded. However, your name will not be linked with the recording, transcription, or your responses during the interview. Is it okay for me to record the conversation today?

If yes, continue to "Background for All Interviews."

If no (interview to restate information that is present on the consent form):

Unfortunately, since you do not agree to the recording of this interview, you won't be able to participate in the study. Thank you for your willingness to participate in the study.

Notes for the Reviewer

Objective of the Interview: The purpose of this interview is to assess the experience of AD and treatment benefit among adults and adolescents with AD in the US, the UK, Canada and Australia who have participated in the Galderma clinical Study RD.06.SPR.118161: a Phase III, multi-center, randomized, double-blind, placebo-controlled trial that assesses the efficacy and safety of nemolizumab (CD141152) in adults and adolescents with moderate-to-severe AD.

Interviews will be conducted within a two-week time window after completion of Week 16.

Written informed consent will be obtained by the clinical site personnel prior to the interviews. Results from these interviews will be documented in a study report and will not be part of the clinical study report (CSR).

Exit Interviews*:* The specific aims of the exit interviews are to:

- The perceived treatment effects and changes in a patient's daily life since receiving the study treatment (placebo or Nemolizumab)
- The meaning and importance of changes in different atopic dermatitis (AD) elements, including associated symptoms
- The relevance and importance of pruritus and sleep disturbance (SD) concepts
- To document treatment satisfaction and subjects' experience with clinical trial participation

The interviews will last approximately 60 minutes and will be conducted in Japanese by moderators trained by Evidera.

Overview of Interview Guide:

The guide is divided into three parts: Part 1. Past and Current Experience of Atopic Dermatitis (AD) and Expectations of the Trial; Part 2. Changes During the Clinical Trial related to AD Symptoms and Sleep Disturbance; Part 3: Overall Perception of Treatment/Clinical Trial

This is a ***semi-structured*** interview guide:

- The discussions during the interview will be largely driven by how much the study participant is willing to share about their experience. Probes are included to encourage the participant when necessary.
- ***The script in the interview guide is meant to help focus the content of the discussion.***
- ***The actual areas of conversation are fluid and may be discussed at moments different from what appears below.***

Depending on the information emerging from the interview and timing, some questions may be modified or not asked by the interviewer. Detailed interviewer training will be provided prior to the first interview to ensure interviewers clearly understand the content of the guide and priority questions. Additional instruction may be added for interviewer training as the interviews progress.

In addition to this interview guide, interviewers will be provided with tables on AD symptoms and impact to complete during the interview.

Interview Guide

Note: The following section includes key points or concepts that will be covered during the interview. This is not a script and the language and wording of the questions can be adjusted to the patient's level of understanding and adapted where appropriate to keep the conversation fluid. If the participant does not understand a question, an example can be provided to facilate understanding. The definition of a meaningful change/ meaningful improvement is also provided.

In each section of the interview there are probes (or follow-up questions) to elicit additional information from patients. Some of these probes may not be asked depending on the flow or the timing of the interview.

The interview guide includes instructions for interviews in red. Questions in green are optional and will be asked if time permits.

Background for All Interviews [5 min]

Great, thanks again for taking the time to speak with me today. As explained in the form that you signed, we are talking to people who have atopic dermatitis (AD) with itching and are experiencing sleep disturbance (SD) who are involved in Galderma's Phase III clinical trial. We are particularly interested in your experiences with your condition, your experiences in the trial, and your impressions of any changes you experienced throughout the study to date.

All of your responses will be anonymous, meaning your name will not be linked with any of your responses. I want to hear about your experience so please share as much information as you feel comfortable with telling me. There are no right or wrong answers.

Your participation is voluntary which means that you do not have to do this. You can skip any question you do not want to answer, and you can choose to stop the interview at any time.

[U.S. PATIENTS ONLY] Although your participation is voluntary, please remember that you will be compensated for your time when you complete the interview.

As a reminder, this interview may take up to 90 min to complete.

I want to remind you that the interview is being recorded. I will try not to use your name from the point I turn the recorder on, and I will ask you to try and not to use your name, the names of your friends, family members or medical doctors, name of the places you live, location of the hospital/ clinic etc. This will help to keep the interview anonymous.

Before we begin, let me suggest some things that will make our discussion more productive.

- Your name and any other personally identifiable information will be kept as confidential and you won't be able to be individually identified in any of the reports that result from the interviews. The information collected during the interview study will be used to help make important decisions about research on this medication in the future.
- My role here is to ask questions and to listen. I'll also be summarizing information at times. I'll ask questions about issues related to your experience and I'll move the discussion from one question to the next, to try to keep us on track so that we can finish within the scheduled time.
- I am not a medical doctor, so I am not qualified to give medical advice. I encourage you to follow-up with your regular doctor if you have any questions about your medication or condition after this interview.
- [U.S. PATIENTS ONLY] When we are done with the interview, I will have the honorarium of $100.
- Please feel free to let me know if you need a break. You can ask me questions at any time.

What to Expect from the Interview:

This interview will occur in two parts. In Part 1, we will explore your experience of the disease (symptoms and impacts) prior to the clinical trial, along with treatments you've tried. In Part 2, we will explore your experiences with the study treatment that you received between baseline **[date]** and Week 16 **[date],** and any perceived effects or changes you've experienced as a result of treatment. We will explore what aspects are most meaningful to you and ask you to rate the significance of any change.

Any questions before we begin?

I will now start audio-recording.

Begin Recorder: This is participant ID *[insert ID number from Clinical Trial here]* for Study EVM-25004 on *[Date].* Do I have your permission to record this interview? ***Affirmative verbal response required.*** And can you please confirm that you completed the informed consent form? ***Affirmative verbal response required.***

Part 1. Past and Current Experience of Atopic Dermatitis (AD) and Expectations of the Trial

First, I would like to ask you questions about your past and current experiences with AD and related symptoms and impacts. We'll then discuss the perceived changes as a result of the clinical trial in Part 2 of this interview.

1.1 Past symptoms of AD [15 min]

Before you started the current study, what are the symptoms you experienced that you think may be related to your AD?

> [Interviewer]: Please make sure patient is describing symptoms BEFORE study entry, within the 2weeks prior to starting the study. Please provide the patient with the date of the baseline visit and ask them to recall experience BEFORE baseline. Please ask them to recall any significant personal, work or other event happened at this period to help them to recall back and anchoring their answer.
>
> We are only interested in the 2 weeks prior to the start of the study and do not need to assess a lifetime of symptoms.
>
> Let the patient spontaneously report symptoms first, and then probe. Obtain the list of symptoms first, then go into more detail (i.e. frequency, duration, etc.) for each symptom individually. Please enter symptoms the patient indicated that they had PRIOR to the current study in Table 1.

For each symptom reported by the patient, please ask if the symptom severity changed since the patient started the clinical trial? [Optional]

For each symptom endorsed by the patient:

- Frequency: How often did you experience this [symptom] before the trial?
- Location: Where on your body did you experience this [symptom]?
- Duration: Did the [symptom] come and go or was it present all the time?
    - If the [symptom] comes and goes: How long did the [symptom] last for?
- Symptom severity:
    - On a scale of 0 to 10, where 0=not severe at all and 10= extremely severe, how bad or severe was this [symptom] when you began the study?
    - Using the same scale, how severe was this symptom for you at Week 16?

> [Interviewer]: Please be ready to remind the patient of their Week 16 visit date. During this interview we are only interested in the patients experience before the trial and between Baseline and Week 16.

Of these symptoms you have mentioned (*such as…list 3-4 symptoms mentioned – see Table 1*), which of the symptoms that you experienced would you call the worst one?

> [Interviewer]: Let the patient spontaneously report what they feel is the worst symptom, and then probe if needed.

Table 1. AD Symptoms Prior to Study Entry

Spontaneous or Probed? (S/P)	Symptom description	Had prior to study? Within 2 weeks (Y/N)	Symptom severity changed since baseline? (Y/N)	Frequency	Location	Duration	Severity at study entry (0-10)	Severity at Week 16 (0-10)
	Itch							
	Dry skin							
	Inflammation/ swelling of the skin							
	Skin Bleeding							
	Open wounds							
	Peeling skin							
	Skin discoloration							
	Burning sensation of the skin							
	Skin Redness							
	Painful skin							
	Sensitive skin							
	Other: specify							
	Other: specify							
	Other: specify							

1.2. Past impact of AD Symptoms on Daily Lives [10 min]

2. Before you started the current study, how did the ADs symptoms affect your daily life? *Probes: sleep disturbance, daily activities, leisure activities, rrelationships affected, emotions, other?*

> [Interviewer]: Please make sure patient is describing impacts BEFORE study entry, within 2-weeks of starting the study. Please provide the patient with the date of the baseline visit and ask them to recall experience BEFORE baseline. Please ask them to recall any significant personal, work or other event happened at this period to help them to recall back and anchoring their answer.
>
> We are only interested in the 2 weeks prior to the start of the study and do not need to assess a lifetime of impacts.
>
> Let the patient spontaneously report impacts first, and then probe based on table. Obtain the list of impacts first, then go into more detail (i.e. changed, resolved, etc.) for each impact individually. Please enter impacts the patient indicated that they had PRIOR to the current study in Table 2.
>
> If subject states multiple categories under the main impact concept, no need to ask follow-up for each sub-category if more than 5 different impacts are reported. Only focus on the main category. If not many impacts are reported, you may have time to go through each sub-category.

3. For each impact reported by the patient, please ask if the impact changed/solved since the patient started the clinical trial? Yes/ no

> [Interviewer]: Please make sure patient is describing change between Baseline and Week 16 only.

4. For each impact reported by the patient, please ask if that impact was related to itch or other symptom? if other, which one?

5. Of all the impact you have been talking about (*such as…list 3-4 impacts mentioned – see Table 2*), which one would you say is the worst one? Why?

> [Interviewer]: Let the patient spontaneously report what they feel is the worst impact, and then probe if needed.

Table 2. AD Impacts Prior to Study Entry

Spontaneous or Probed? (S/P)	Impact description	Had prior to study? Within 2-weeks. (Y/N)	Impact Changed since baseline to Week 16? (Y/N)	Resolved? Between Baseline and Week 16 only (Y/N)	Did this impact relate to itch or other AD symptoms? (Y/N/Unknown) (If Y/N, which one?)
	Sleep disturbance				
	☐ Falling asleep				
	☐ Staying asleep				
	☐ Night-time awakening				
	☐ Feeling like as you did not get enough sleep				
	☐ Early morning awakening				
	☐ Feeling unrested/ unrefreshed				
	☐ Daytime fatigue / tired during the day				
	☐ Trouble staying awake during the day				
	☐ Feeling drowsy or sleepy during the day				
	☐ Need for a nap during the day				
	☐ Other: specify				
	Daily activities				
	☐ Daily routine				
	☐ Chores/ housework/ gardening				
	☐ Working				
	☐ Studying				
	☐ Other: specify				
	Leisure activities				
	☐ Social activities limited e.g. going to the cinema, pub or out to dinner				
	☐ Hobbies				
	☐ Sport (swimming, other)				
	☐ Other, specify				
	Relationships affected				
	☐ Relationship with spouse				
	☐ Relationship with family				
	☐ Relationship with friends & acquaintances				
	☐ Work relationship / school relationship				
	☐ other, specify				
	☐ other, specify				
	☐ other, specify				

Spontaneous or Probed? (S/P)	Impact description	Had prior to study? Within 2-weeks. (Y/N)	Impact Changed since baseline to Week 16? (Y/N)	Resolved? Between Baseline and Week 16 only (Y/N)	Did this impact relate to itch or other AD symptoms? (Y/N/Unknown) (If Y/N, which one?)
	Emotions ☐ Anxiety ☐ Embarrassment				
	☐ Depression				
	☐ Worry				
	☐ Stress				
	☐ Frustration				
	☐ Other, specify				
	Other: specify				
	Other: specify				
	Other: specify				
	Other: specify				
	Other: specify				
	Other: specify				
	Other: specify				

1.3 Experience of AD Treatment [5 min] [Optional]

Now I would like to ask you some questions about previous treatments you have had for AD PRIOR to enrollment in the trial.

[Interviewer]: Only probe on previous treatment (latest treatment only). We do not need a comprehensive list of all treatments ever used.

1. Prior to your involvement in the clinical trial did you use any treatments specifically for your AD?
    - If so, what were they? How much did they help to manage your itch? How much did they help to manage your sleep disturbance?
    - What would you look for in an ideal treatment?
    - What factors do you consider when selecting a course of treatment? What type of things do you take into considerations when you are deciding how successful a treatment is or could be?

1.4 Decision and Expectations of the Trial [5 min]

I would now like to ask you some questions about your decision to enroll in this trial.

1. What made you decide to enroll in Galderma's clinical trial?
2. Did you have any expectations when entering the clinical trial? If so, what were they?
3. Did you have any concerns when entering the clinical trial? If so, what were they?
4. What were you hoping for in terms of a change in your **itch** from the study treatment?
5. What were you hoping for in terms of change in your **sleep disturbance** from the study treatment?

Part 2. Changes During the Clinical Trial related to AD Symptoms and Sleep Disturbance

2.1 Exploration of NEW Symptoms [5 min]

So far, we have been talking about symptoms you had before the study. Now, I would like to know about any NEW SYMPTOMS you had since the being in this study that were new for you (i.e. had not experienced before the study). Can you describe the new symptoms?

> [Interviewer]: Please make sure you clarify with the patient that we are only interested in new symptoms from Baseline to Week 16. Please remind the baseline and week 16 dates if necessary.
>
> Let the patient spontaneously report new symptoms and then probe. Obtain the list of new symptoms first, then go into more detail (i.e. frequency, duration, etc.) for each symptom individually. Enter NEW symptoms the patient indicated that they had during the study up to Week 16 in Table 3.

For each new symptom (Table 3)

1. For each symptom endorsed:
    a. When this [**new symptom**] was first noticed in the trial?
    b. Frequency: How often did you experience *[symptom]* during the trial?
    c. *Location: Where on your body did you experience [symptom]?*
    d. *Duration: Did the [symptom] come and go or was it present all the time?*
    e. *If [symptom] comes and goes:* How long did the *[symptom]* last for?
    f. Severity:
        i. On a scale of 0 to 10, where 0=not severe at all and 10= extremely severe, how bad, severe was this symptom when it was at its worst during the study (Baseline to Week 16).
        ii. Using the same scale, how severe is this symptom for you **at Week 16**?

Table 3. New Symptoms Since Being in the Study

Symptom description	Point in CT that this new symptom was noticed (x weeks)	Frequency	Location	Duration	Severity at its worst during the trial (0 – 10)	Severity at Week 16 (0-10)
Sensitive skin						
Other: specify						
Other: specify						
Other: specify						

2.2. Exploration of Meaningful Changes: Symptoms (New and previous Symptoms) [15 min]

Now I would like to discuss your experience in Galderma's clinical trial as it relates to any changes you may have experienced with regard to your AD symptoms. We are only interested in your experience between Baseline to Week 16.

> [Interviewer]: Please recall any personal, work or other event reported by the patient soon after they started the trial to help them to recall back and anchoring their answer.
>
> Suggestion: Pause and take a moment to write all new and old symptoms down on Table 4 that they indicated changed (up to Week 16). For example, if itching was a 9 at baseline and a 9 at week 16, you do not need to follow-up in Table 4. Just confirm verbally there was no change.
>
> But if Itching was a 9 at baseline and a 4 at Week 16, you will proceed with all the follow-up questions in this section.

1. At the beginning of the interview, you mentioned [X symptoms] experienced prior to study entry and during the trial you mentioned [X new symptoms].

> [Interviewer]: please report the symptoms that the patient indicated had changed since they started the clinical trial in the Table 4.
>
> [Interviewer]: for each symptom change endorsed, please probe for improvement and worsening when appropriate

For each symptom change endorsed (prior to study entry and during the trial)

a. What specifically did you notice? Probe for the nature of the change

b. When during the trial did you first notice the change? Probe weeks into the trial (up to Week 16)

   i. Please give us some examples of how you noticed the change? What made you realize there was a change?

c. Has the change stayed consistent during the trial?

   i. If no: Did it come and go? If so, how long did it stay? Did it disappear or increase/decrease?)

d. Rating of the change (between Baseline to Week 16) using a Global Assessment of Change (GAC) scale: "much worse," "a little worse," "the same," "a little better," , or "much better"

   i. Those who reported worsening on GAC, ask: Is this increase in [symptom] a meaningful or important change for you?' (Yes/No)

> [Interviewer]: If the patient has difficulties understanding what a meaningful change means, please tell them that this is a change, positive or negative, that results in a change in their life, in the way they feel, function and their capacity to do things.

   - In what ways? Can you provide some examples? *Probe for examples/participant rationale*

[Interviewer]: Please probe for the following examples. If yes, was the change good or bad? How big was that change? Was the amount of change important for you? How did it affect your life?

ii. Those who reported improvement on GAC, ask: Is this decrease in [symptom] a meaningful change for you? (Yes/No)

- In what ways? Can you provide some examples?

Table 4 (section2.2) AD Symptoms (New and previous) Meaningful Changes

Symptom description	What specifically did you notice?	Improved or Worsened?	Point in CT that change was noticed (x weeks)	Constant change Y/N	"much worse," "a little worse," "the same," "a little better," , or "much better"	Is this increase meaningful and important?	In what ways?
Itch							
Dry skin							
Inflammation/ swelling of the skin							
Skin Bleeding							
Open wounds							
Peeling skin							
Skin discoloration							
Burning sensation of the skin							
Skin Redness							
Painful skin							
Sensitive skin							
Other: specify							
Other: specify							
Other: specify							

Symptom description	What specifically did you notice?	Improved or Worsened?	Point in CT that change was noticed (x weeks)	Constant change Y/N	"much worse," "a little worse," "the same," "a little better," , or "much better"	Is this increase meaningful and important?	In what ways?
Other: specify							
Other: specify							
Other: specify							
Other: specify							
Other: specify							
Other: specify							
Other: specify							
Other: specify							
Other: specify							
Other: specify							
Other: specify							
Other: specify							
Other: specify							
Other: specify							

2.3 Exploration of NEW Impacts [5 min]

So far, we have been talking about impacts you had before the study. Now, I would like to know about any new impacts you had since the beginning of this study (up to Week 16) that were new for you (had not experienced before the study). Can you describe these new impacts?

> [Interviewer]: Please make sure you clarify with the patient that we are only interested in experience from Baseline to Week 16. Please remind the baseline and week 16 dates if necessary.
>
> Let the patient spontaneously report new impacts first, and then probe. Obtain the list of new impacts first, then go into more detail for each impact individually. Enter NEW impacts the patient indicated that they had during the study in Table 5.

1. For each impact reported by the patient, please ask if the impact worsen, improved or was resolved during the trial?
2. When this new impact was first noticed?

Table 5. New Impacts Since Being in the Study

New Impact description	Point in CT that this new symptom was noticed (x weeks)	Improved or Worsened?	Resolved? Between Baseline and Week 16. (Y/N)

2.4 Exploration of meaningful change in impacts (NEW and PREVIOUS impacts) [15 min]

Now I would like to discuss your experience in Galderma's clinical trial as it relates to any changes you may have experienced with regards to impacts.

3. Did you notice any changes in how CTCL symptoms **impact** your day-today life since you started the clinical trial or during the trial? (*Probe: for example, prior to your entry into the clinical trial you mention x impact; has that changed?)* ***(Table 6)***
4. At the beginning of the interview, you mentioned [X impacts] experienced prior to study entry during the trial you mentioned [X new impacts].

> [Interviewer]: Please report the impacts the patient indicated that they had changed since they started the clinical trial or during the trial (up to Week 16) in the Table 6.

> Suggestion: Pause and take a moment to write all new and old impacts down on Table 6 that they indicated changed (up to Week 16). For example, if embarrassment was a 9 at baseline and a 9 at week 16, you do not need to follow-up in Table 6. Just confirm verbally there was no change.
>
> But if embarrassment was a 9 at baseline and a 4 at Week 16, you will proceed with all the follow-up questions in this section.

[Interviewer]: for each impact change endorsed, please probe for improvement and worsening when appropriate

For each impact endorsed:

a. What specifically did you notice? *Probe for the nature of the change*

b. When during the trial did you first notice the change? *Probe weeks into the trial*

   i. What are some examples of how you noticed the change? What made you realize there was a change?

c. Has the change stayed consistent during the trial?

   i. If no: Did it come and go? If so, how long did it stay? Did it disappear or increase/decrease?)

d. Rating of the change using a GAC scale: "much worse", "a little worse", "the same", "a little better", or "much better"

   i. Those who reported worsening on GAC then ask: Is this increase in [impact] a meaningful change you?' (Yes/No)

      [Interviewer]: If the patient has difficulties understanding what a meaningful change means, please tell them that this is a change, positive or negative, that results in a change in their life, in the way they feel, function and their capacity to do things.

      - In what ways? Can you provide some examples? *Probe for examples/participant rationale*

      [Interviewer]: Please probe for the following examples. If yes, was the change good or bad? How big was that change? Was the amount of change important for you? How did it affect your life?

   ii. Those who reported improvement on GAC were then asked: Is this decrease in [impact] a meaningful change for you? (Yes/No)

      - In what ways? Can you provide some examples? *Probe for examples/participant rationale*

Table 6. Change in Impacts After Starting the Clinical Trial (Between Baseline and Week 16) [From Tables 2 and 5]

Impact	Improved or Worsened?	Point in CT that change was noticed (x weeks)	Constant change Y/N	How much worse or better?*	Is this increase in [impact] a meaningful change for you?' (Yes/No) – In what ways?	Is this increase meaningful and important?	In what ways (add descriptions)

*"much worse", "a little worse", "the same", "a little better", or "much better"

Impact	Improved or Worsened?	Point in CT that change was noticed (x weeks)	Constant change Y/N	How much worse or better?*	Is this increase in [impact] a meaningful change for you?' (Yes/No) – In what ways?	Is this increase meaningful and important?	In what ways (add descriptions)

2.5 PRO Data [10 min]

At the beginning of the trial and throughout the trial you completed a few sleep questionnaires, including the Sleep Diary. For the next phase of the interview, I would like to explore with you which changes on the sleep diary questions would matter to you.

Thank you. For the next phase of the interview, I would like to explore with you which changes in the sleep diary questions would matter to you.

Sleep Diary

Item 3:

The item 3 of the sleep diary asks about the time it takes you to fall asleep.

Before entering in the clinical trial, how long did it take you to fall asleep during a typical nighttime sleep?

a. Were these difficulties usually related to AD symptoms or other things?

iii. What would be the smallest improvement (in time gained of sleep) that would be meaningful or important to you? Why?

> [Interviewer]: If the patient has difficulties understanding what a meaningful improvement means, please tell them that this is an improvement that results in a positive change in their life (emotions or capacity to do things).

b. What would that change or improvement of ***[XXX improvement reported by the patient]*** in your sleep mean for you in terms of quality of sleep?

Item 4:

The item 4 of the sleep diary asks about the number of times you wake up during the night, due to the symptoms of atopic dermatitis (for example itching, burning).

Before entering in the clinical trial, how many times did you usually woke up due to AD symptoms during a typical nighttime sleep?

iv. What would be the smallest improvement (in number of awakenings due to AD) that would be meaningful or important to you? Why?

> [Interviewer]: If the patient has difficulties understanding what a meaningful improvement means, please tell them that this is an improvement that results in a positive change in their life (emotions or capacity to do things).

c. What would that change or improvement of ***[XXX improvement reported by the patient]*** in your sleep mean for you in terms of quality of sleep?

Item 5

The item 5 of the diary asks about the total time your nighttime awakenings due to AD symptoms last.

d. Before entering in the clinical trial, how long did your awakenings related to AD symptoms usually last during a typical nighttime sleep?

e. What would be the smallest improvement (in time gained of sleep) that would be meaningful or important to you? Why?

> [Interviewer]: If the patient has difficulties understanding what a meaningful improvement means, please tell them that this is an improvement that results in a positive change in their life (emotions or capacity to do things).

f. What would that change or improvement of ***[XXX improvement reported by the patient]*** in your sleep mean for you in terms of quality of sleep?

Items 6/7:

The sleep diary also asks about the awakenings related to other things (for example to drink water, to go to the bathroom).

g. Based on your experience, can you please describe the differences between awakenings related to AD symptoms and awakenings related other things?

h. Does the experience of a nighttime awakening related to AD and the experience a nighttime awakening related to other things mean the same for you? Why or why not?

> [Interviewer]: If the patient has difficulties understanding this question, ask them when they wake up during the night because of their AD, if the duration and discomfort of this awakening is the same as when they wake up during the night to drink, go to the bathroom or for other things not related to their AD.

Part 3: Overall Perception of Treatment/Clinical Trial

3.1 Treatment Perception [5 min]

Now, switching gears to your general impressions of the treatment between Baseline and Week 16.

1. Overall, what did you like and what did you not like about the treatment?
2. Overall, would you say the treatment you received helped you in the management of your condition?
   a. If yes, why?
   b. If no, why?

3. Overall, was the treatment able to meet your expectations?
4. Overall, how satisfied were you with your treatment?
    a. On a scale of 0 to 10, please rate how satisfied you currently are with the study treatment. A zero would mean you are not satisfied at all and a 10 mean you are extremely satisfied.
5. What would need to change to consider the treatment successful?
6. How does the treatment you received in the clinical trial compare to the treatment(s) you took previously? *Probe on differences in efficacy and preferences for mode of administration*
7. Did you experience any effects/changes from the treatment that you did not expect?
8. Based on your experience, would you recommend this treatment to others with itch and sleep disturbance?
    a. If yes, why?
    b. If no, why?

3.2 Trial Perception [Optional] [5 min]

And finally, I would like to ask about your general thoughts on the clinical trial overall.

1. Overall, what did you think about the clinical trial? *Probe on experience with study visits, study procedures, study assessments (frequency and length of patient questionnaires)*
2. Did being a part of the trial impact your day-to-day life? *Probe for examples; Probe about the nature, extent, frequency, and duration of impacts*
3. Anything else you would like to share that I did not ask about related to your experience with AD, itch, sleep disturbance, or the clinical trial?

Thank you for your time and for all the insightful information and experiences you have shared with us today. *Answer any questions or provide information, as needed about the payment card.*