Title Page

Protocol Title: A Randomized, Multicenter, Evaluator-blind, Controlled Study to Evaluate the Safety and Effectiveness of JUVÉDERM VOLITE™ XC Injectable Gel for the Improvement in Cheek Skin Smoothness

Protocol Number: 1867-701-008 Amendment 3

Compound Number: JUVÉDERM VOLITE™ XC Injectable Gel

Sponsor Name: Allergan

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SAP Version History

This SAP amendment is based on the protocol Amendment 3 approved on 25 November 2019 and original SAP approved on March 1, 2020. The changes are described below:

SAP Version History Summary			
SAP Version	**Approval Date**	**Change**	**Rationale**
1	March 1, 2020	Not Applicable	Original version
2 (amendment)		Sections 4, 5.1, 5.3.2, 5.4, 5.5, 5.6.3, 5.6.5, 5.6.6, 5.6.7, 5.7.1, 6.3.3, 6.4.1.2, 6.4.2, 6.5.2, 6.5.4, and 6.5.6	Details are described in Appendix 2, Changes to SAP version 1 Analyses

1. Introduction

This Statistical Analysis Plan (SAP) provides a technical and detailed elaboration of the statistical analyses of the effectiveness and safety data as outlined and specified in Study 1867-701-008 protocol Amendment 3 (dated 25 November 2019). Specifications of tables, figures, and data listings are contained in a separate document.

1.1. Objectives and Endpoints

Please refer to Section 4.1 of study protocol.

1.2. Study Design

Study 1867-701-008 is a multicenter, evaluator-blind, controlled, parallel-design, prospective study of adults seeking improvement in cheek skin smoothness. The cheek skin smoothness will be assessed based on ACSS scores, ranging from 0 to 4 (none to extreme). Participants randomized to JUVÉDERM VOLITE XC will receive injectable gel in multiple microdepot injections across both cheeks. The following treatment groups are defined for this study:

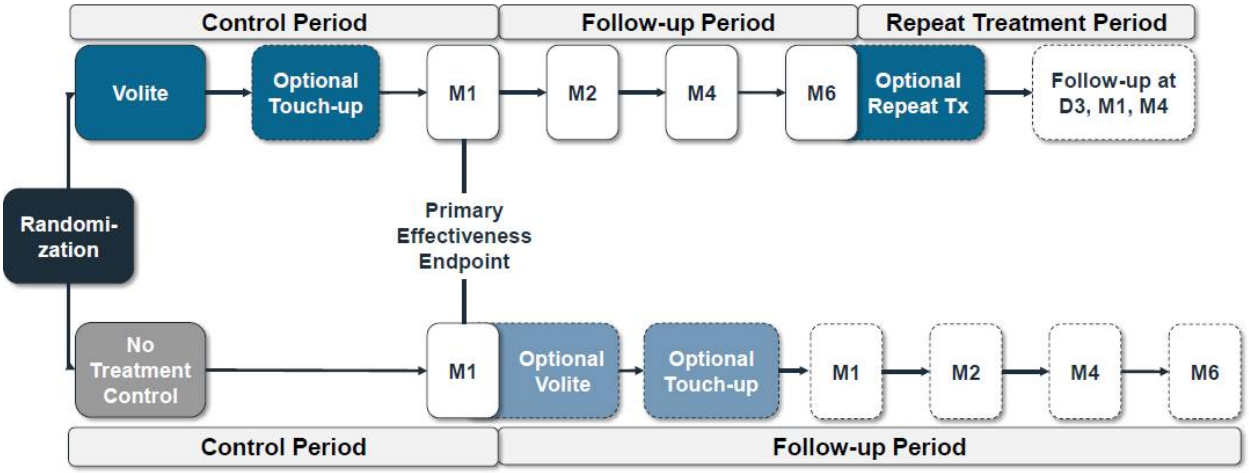
- VOLITE: JUVÉDERM VOLITE™ XC injectable gel
- Control: No-treatment

Up to 263 participants will be enrolled, and approximately 210 participants from maximum 20 investigational sites will be randomized at a 2:1 ratio to treatment group and control group. Each site will have a blinded evaluating investigator (EI) and a principal investigator (PI) who is responsible for the overall conduct of the study at that site and may also be the treating investigator (TI). The TI performs all study treatments, and the blinded EI evaluates ACSS, AFLS, and skin hydration measurements.

The study design is presented in Figure 1-1. Treatment group participants receive initial treatment and optional touch-up treatment at 30 days if needed to achieve optimal correction. Follow-up visits are 3 days after each treatment (collection of only safety data) and at Months 1, 2, 4, and 6 after the preceding treatment. Participants exit the study at Month 6 or receive repeat treatment and are followed at Day 3 and Months 1 and 4 after repeat treatment. Control group participants are followed for 1 month after randomization (the 'no-treatment control' period) and then either exit the study or receive optional treatment (initial and touch-up, if needed) in the delayed treatment period. Post-treatment follow-up visits are 3 days after each treatment and at Months 1, 2, 4, and 6 after the preceding treatment.

To ensure adequate enrollment of participants with Fitzpatrick skin phototype V and VI, up to 10 participants may be enrolled in the Fitzpatrick V/VI safety cohort with less stringent inclusion criteria (see protocol Section 6.1) and followed for safety only.

Figure 1-1 Study Design



2. Statistical Hypotheses

The primary effectiveness variable is the cheek skin smoothness based on the ACSS evaluated by EIs. The primary effectiveness endpoint is the ACSS responders at Month 1 defined as a participant who achieves at least a 1-point improvement from baseline on both cheeks based on ACSS. Month 1 refers to 1 month after the preceding treatment (initial or touch-up) for participants in the JUVÉDERM VOLITE XC treatment group or 1 month after randomization for participants in the no-treatment control group.

The null hypothesis is that there is no difference between the JUVÉDERM VOLITE XC treatment group and the no-treatment control group in the ACSS responder rate at Month 1. The alternative hypothesis is that there is difference between the JUVÉDERM VOLITE XC treatment group and the no-treatment control group in the ACSS responder rate at Month 1. These hypotheses are stated as:

$$H_o: P_v - P_c = 0$$

$$H_a: P_v - P_c > 0 \text{ or } P_v - P_c < 0$$

where Pv and Pc denote the responder rates for the JUVÉDERM VOLITE XC group at Month 1 after the preceding treatment (initial or touch-up) and for the no-treatment control group at Month 1 after randomization, respectively. The treatment effects between JUVÉDERM VOLITE XC and the no-treatment control group will be compared using the statistical method described in Section 5.3.2. If the 2-sided p-value is less than 0.05 and the responder rate is greater for JUVÉDERM VOLITE XC than for the no-treatment control group, then JUVÉDERM VOLITE XC will be considered superior to the no-treatment control group.

3. Sample Size Determination

A sample size of 112 participants in the treatment group and 56 participants in the control group will provide 99.9% power to detect a difference of at least 40% in the responder rates on the ACSS between the groups, based on a 2-sided Fisher's exact test at the 5% level. The treatment group is assumed to have at least an 80% responder rate at Month 1, and the control group is assumed to have at most a 40% responder rate. The assumptions of responder rates are estimated from Allergan Study V12-001. Accounting for participant attrition of 20% during the study, 210 participants will be randomized at a 2:1 ratio to treatment group and control group. Randomization will occur within each study site.

Among the 210 participants randomized, at least 135 participants are expected to have a baseline AFLS score of 2 on both cheeks or 3 on both cheeks. The number of participants with baseline AFLS score of 0, 1, or 4 on either cheek, or 2 on one cheek and 3 on the other cheek is not expected to exceed 75. Assuming at least 65% of participants will have baseline AFLS score of 2 on both cheeks or 3 on both cheeks, 72 participants in treatment group and 36 participants in control group will provide 94.4% power to detect a difference of at least 35% in the responder rates on AFLS between the treatment groups, based on a 2-sided Fisher's exact test at the 5% level. The treatment group is assumed to have at least an 80% responder rate at Month 1, and the control group is assumed to have at most a 45% responder rate. The assumptions of responder rates are estimated from Allergan Study V12-001.

The sample size calculations used an inequality test for 2 proportions to demonstrate that the treatment group is superior to the control group.

Assuming 119 participants from the treatment group and 28 participants from the control group will be treated, a total of 147 treated participants will provide 95% power to detect an AE related to treatment with an incidence rate of 2% in the population using a 1-sided exact binomial test at the 2.5% level.

The commercial software, PASS (2008, Version 8.0.13), was used for the power calculations.

4. Populations for Analysis

The analysis populations will consist of participants as defined in Table 4-1.

Table 4-1 Analysis Populations

Population	Definition	Study Treatment Assignment
mITT	All randomized participants who have baseline assessment on the ACSS scale for both cheeks, and are not in the Fitzpatrick V/VI safety cohort (see the definition below)	As randomized
Observed Primary Endpoint	All mITT participants who have Month 1 assessment on the ACSS scale for both cheeks	As randomized
Safety	All participants who are randomized and received study intervention (VOLITE or no treatment)	As treated
VOLITE Treated (VT)	Participants randomized and received VOLITE treatment at the beginning of the Control Period, or Participants randomized and received optional VOLITE treatment after the Control Period.	As treated
VOLITE Repeat Treatment (VRT)	Participants in the VT who received VOLITE repeat treatment	As treated
Fitzpatrick Safety Cohort	Participants who were enrolled under protocol amendment 2 or above with Fitzpatrick skin phototype V or VI and meet any of the conditions including (1) baseline ACSS score of 1 in either cheek, (2) asymmetric baseline ACSS score of 2 or 3, or (3) FACE-Q overall converted score greater than 69	As treated

5. Statistical Analyses

5.1. General Considerations

- The primary analysis will be performed after the database is locked and randomization schedule is released.
- To account for different timing of VOLITE treatment and comparable time frame of data collection to enhance interpretability of effectiveness and safety analyses, the statistical analyses will be performed by the study periods defined below in Table 5-1. For participants randomized to the treatment group, the Treated Period (TP) is the Control Period (CP) plus the Follow-up Period; for participants randomized to the control group, the TP is the Follow-up Period composed of the delayed treatment period plus the delayed treatment follow-up period (Figure 1-1). Follow-up Period starts on the end date of CP + 1 and ends on the same day as TP.

Table 5-1 Definition of the Control, Treatment, and Repeat Treatment Periods by Randomization Group

Randomization Group	Period	Treatment Group Label	Start Date	End Date
Treatment	Control Period (CP)	VOLITE	Initial treatment date	The end date is the date of the Month 1 assessment: • If multiple assessments fall into Month 1 window, the date of the assessment included in the Month 1 analysis will be used as end date. • For participants who exit before Month 1, the end date is study exit date. • For participants with a missing assessment at Month 1, the end date is the target day for Month 1.
	Treated Period (TP)	VOLITE	Initial treatment date	Date of repeat treatment or the study exit date, whichever is earlier
	Repeat Treatment Period (RP)	VOLITE	Repeat treatment date	Study exit date
Control	CP	Control	Randomization date	For participants who do not receive optional treatment: • If multiple assessments fall into Month 1window, the date of the assessment included in the Month 1 analysis will be used as end date. • For participants who exit before Month 1, the end date is study exit date. • For participants with missing assessment at Month 1, the target day for Month 1 (Day 31) will be the end date. For participants who receive optional treatment: the end date is the date of optional treatment.
	TP	VOLITE Post-Control	Optional treatment date	Study exit date

- The start and end of treatment periods listed above for the mis-treated participants (ie., randomized to Treatment and did not receive Volite or randomized to Control and was treated with Volite prior to the primary timepoint) will be determined based on the treatment received.
- For CP, effectiveness analyses and baseline characteristics will be performed on the mITT population using the "as-randomized" assignment.

- For TP, effectiveness and safety summaries will be performed on the VT population by treatment group.
- For RP, effectiveness and safety summaries will be performed on the VRT population.
- The baseline for applicable effectiveness endpoints and safety parameters will be the last non-missing assessment on or before the latter of randomization date or first treatment date in the control period
- The change from baseline values will be computed as the post-baseline value minus the baseline value.
- Continuous variables will be summarized by number of participants with observed values (n), mean, standard deviation (SD), median, 1st and 3rd quartiles (Q1, Q3), minimum (min), and maximum (max).Categorical variables will be summarized by the number of participants with observed values or events (n), frequency count (N1), and percentage of participants with observed values or events.
- All statistical hypothesis tests will be performed at the 2-sided 5% significance level, unless stated otherwise.
- In general, statistical analyses will be performed using SAS version 9.4 or higher. Adverse events (AEs) and medical history will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) version 22.1 or higher.
- WHO Drug Dictionary will be used to code medications.

5.2. Participant Dispositions

The number of participants in each of the 6 study populations (mITT, Completers, Safety, VT, VRT, and Fitzpatrick safety cohort) will be summarized by treatment group.

The summary of study disposition will be provided for all screened participants overall or by study intervention group as randomized for the following:

- Number of participants screened (overall)
- Number of participants randomized; this number will be used as the denominator to compute the following percentages
- Number of participants treated as randomized
- Number of participants not treated as randomized

For mITT Population during CP

- Number of participants completed Control Period
- Number of participants discontinued during Control Period
- Reasons for discontinuation during Control Period

For VT Population after CP

- Number of participants who continued after Control Period
- Number of participants who completed the Follow-up Period
- Number of participants who discontinued during the Follow-up Period
- Reasons for discontinuation during the Follow-up Period

For VRT population during the RP

- Number of participants who received repeat treatment
- Number of participants who completed the RP
- Number of participants who discontinued during the RP
- Reasons for discontinuation during the RP

For mITT Population during the study

- Number of participants who completed the study
- Number of participants who discontinued from the study
- Reasons for discontinuation from the study

A participant is considered to have completed the study if he/she has completed all phases of the study including the last visit. Treatment group participants who elect not to receive repeat treatment are considered completers if they complete the Month 6 visit. Control group participants who elect not to receive treatment are considered completers if they complete the Month 1 visit.

5.3. Primary Effectiveness Endpoint Analysis

5.3.1. Definition of Endpoint

The primary effectiveness endpoint is the ACSS responder status at Month 1 in CP based on EI's assessment. A responder is defined as a participant who achieves at least 1-point improvement (reduction) from baseline on the ACSS scale (described in Table 5-2) on both cheeks.

Table 5-2 Allergan Cheek Smoothness Scale

Score	Grade	Description
0	None	Smooth visual skin texture
1	Minimal	Slightly coarse and uneven visual skin texture
2	Moderate	Moderately coarse and uneven visual skin texture; may have early elastosis
3	Severe	Severely coarse visual skin texture, crosshatched fine lines; may have some elastosis
4	Extreme	Extremely coarse visual skin texture, crosshatched deep creases; extreme elastosis

5.3.2. Main Analytical Approach

The missing data in ACSS at Month 1 of CP will be imputed using the Multiple Imputation (MI) method for the mITT population as follows:

Step 1: The missing data will be imputed by cheek side and treatment group using the Fully Conditional Specification (FCS) method with seed = 820403 and nimpute = 30 based on the following model:

$$\text{Month 1 ACSS} = \beta_0 + \beta_1 \times \text{Age} + \beta_2 \times \text{Baseline ACSS}$$

Step 2: After imputation, the changes from baseline will be calculated, from which the responder status in ACSS at Month 1 of CP will be determined.

Step 3: Each complete dataset obtained from Steps 1 and 2 will be analyzed using SAS procedure FREQ

Step 4: The pooled results will be obtained using PROC MIANALYZE

The number and proportion of participants who achieved at least 1-point improvement from baseline at Month 1 of CP will be tabulated by treatment group. The aggregated responder rates by treatment group and the associated p-value and 95% CI estimated based on the normal approximation to assess the difference in the ACSS responder rate at Month 1 of CP between JUVÉDERM VOLITE XC and the no-treatment control will be presented. If the 2-sided p-value is less than 0.05, then the ACSS responder rate at Month 1 in JUVÉDERM VOLITE XC is statistically significantly different from that in the no-treatment control group during the control period. Furthermore, if the responder rate is greater for JUVÉDERM VOLITE XC than the no-treatment control group, then VOLITE will be considered superior to the no-treatment control group.

The detailed SAS codes are as follows:

```
proc mi data=adeff seed=820403 nimpute=30 out=mi;
        by trt01p cheek;
        class acss0 acss1;
        fcs logistic(/details);
        var age acss0 acss1;
run;
data lmi rmi; *separate imputed datasets by cheek side;
        set mi;
        if cheek='Left' then output lmi;
        if cheek='Right' then output rmi;
run;
data all; *obtain responder status variable;
        merge lmi rmi;
```

```
        by _imputation_ subjid;
        ldiff=lacss0-lacss1;
        rdiff=racss0-racss1;
        resp=0;
        if ldiff >= 1 and rdiff>=1 then resp=1;
run;
ods output RiskDiffCol2=risk(where=(index(row,'Total')=0));
proc freq data=all;
        by _imputation_;
        tables trt01p*resp/riskdiff;
run;
proc sort data=risk; by row;
ods output VarianceInfo=Variance1;
ods output ParameterEstimates=Param1;
proc mianalyze data=risk;
        by row;
        modeleffects risk;
        stderr ase;
run;
```

5.3.3. Sensitivity Analyses

Two sensitivity analyses of the primary effectiveness endpoint, the ACSS responder status at Month 1 in CP based on EI's assessment, will be performed as follows:

- A tipping point analysis using the mITT population will be conducted to evaluate all possible combinations of participants with missing Month 1 ACSS assessments counted as responders in both treatment groups. A diagram of 2-sided p-values based on the Fisher's exact test with the x-axis and y-axis displaying the number of imputed responders out of the total number of participants with missing Month 1 ACSS assessment in VOLITE and Control group, respectively and the p-values ≤0.05 and >0.05 in different colors will be presented.
- The ACSS responder at Month 1 of CP will be analyzed using the Observed Primary Endpoint population. The number and proportion of participants of ACSS responder will be tabulated by treatment group. The between-group difference in the responder rate, 95% CI for the responder rate difference, and p-value based on the Fisher's exact test will be presented.

5.4. Secondary Effectiveness Endpoints Analysis

5.4.1. Secondary Effectiveness Endpoints

The secondary effectiveness endpoints are change from baseline in FACE-Q Satisfaction with Skin overall converted score at Month 1 during the CP and AFLS responder at Month 1 during the CP.

Each participant's responses to the 12 items on the FACE-Q Satisfaction with Skin questionnaire will be summed and converted to a scale score that ranges from 0 to 100 (higher score indicates more satisfaction) using the algorithm developed by the FACE-Q scale developers (see Sections 6.5.1 and 6.5.2 for details of derivation). The mean change from baseline in FACE-Q overall converted score at Month 1 will be calculated. The change from baseline value will be computed as the value for the postbaseline visit minus the baseline value. The analysis will be conducted using observed data (eg, no imputation for missing baseline or Month 1 FACE-Q scale scores).

An AFLS responder is defined as participant who achieves at least 1-point improvement from baseline on the AFLS scale (see Table 5-3) on both cheeks.

Table 5-3 Allergan Fine Lines Scale

Score	Grade	Description
0	None	No fine lines
1	Minimal	1-2 superficial lines
2	Moderate	3-5 superficial lines
3	Severe	Greater than 5 superficial lines; no crosshatching
4	Diffuse	Diffuse superficial lines; crosshatching

5.4.2. Main Analytical Approach

For the secondary effectiveness endpoint of change from baseline in FACE-Q Satisfaction with Skin overall converted score at Month 1, a 2-sided 2-sample t-test, if the normality assumption holds, otherwise, the Wilcoxon rank-sum test will be used to compare mean change from baseline values between treatment and control groups using the mITT population.

For the secondary effectiveness endpoint of AFLS responder status at Month 1, the 95% CI will be provided for the proportion of responders for each treatment group. For comparison of treatment group versus control group at Month 1, the responder rate difference, 95% CI for the risk difference and p-value will be estimated based on Fisher's exact test using the mITT population with baseline AFLS score of 2 on both cheeks or 3 on both cheeks.

5.5. Other Effectiveness Endpoints Analysis

The other effectiveness endpoints listed in Table 5-4 will be summarized descriptively based on the observed data.

The analyses of CP will be performed for the mITT population at Baseline and Month 1. The analyses of TP will be performed for the VT population at Baseline and Months 1, 2, 4, and 6.

The analyses of RP will be performed for the VRT population at Baseline and Months 1 and 4 post the repeat treatment.

The composite responder status is defined based on ACSS and FACE-Q Satisfaction with Skin Questionnaire overall converted score. A participant is counted as a composite responder if both criteria listed below are met:

- ACSS criterion: A participant with at least 1-point reduction from baseline in ACSS on both cheeks will be considered as an ACSS responder
- FACE-Q satisfaction with skin responder: A participant with change from baseline in FACE-Q overall converted score ≥ half of standard deviation of FACE-Q overall converted score at baseline (Pusic 2013)

Table 5-4 Other Effectiveness Analyses

Endpoint	Description	Analysis Period	Methodology
ACSS responder status as assessed by EI	Number (%) of responders by treatment group	TP, RP	Frequency counts and percentages
Raw value and change from baseline in ACSS	Summary by treatment group	CP, TP, RP	Continuous descriptive statistics
Raw value and change from baseline in FACE-Q Satisfaction with Skin questionnaire overall converted score	Summary by treatment group	TP, RP	Continuous descriptive statistics
Item score of FACE-Q Satisfaction with Skin questionnaire and aggregated categories of "satisfied" and "dissatisfied"	Number (%) of each response category by treatment for each of 12 individual items	CP, TP, RP	Frequency counts and percentages
AFLS responder status as assessed by EI	Number (%) of responders by treatment group	TP, RP	Frequency counts and percentages
Raw value and change from baseline in AFLS	Summary by treatment group	CP, TP, RP	Continuous descriptive statistics
Raw value and change from baseline in FACE-Q Appraisal of Lines questionnaire overall converted score (see Section 6.5.3 and Section 6.5.4)	Summary by treatment group	CP, TP, RP	Continuous descriptive statistics
Item score of FACE-Q Appraisal of Lines questionnaire and aggregated categories of "satisfied" and "dissatisfied"	Number (%) of each response category by treatment for each of 12 individual items	CP, TP, RP	Frequency counts and percentages
Participant assessment of the natural look of the cheek skin on an 11-point scale ranging from 0 (unnatural looking) to 10 (natural looking)	Summary by treatment group	TP, RP	Frequency counts, percentages and Continuous descriptive statistics
Participant assessment of the natural feel of the cheek skin on an 11-point scale ranging from 0 (unnatural feeling) to 10 (natural feeling)	Summary by treatment group	TP, RP	Frequency counts, percentages and Continuous descriptive statistics
GAIS responder status defined as "improved" or "much improved" as assessed by participant (Table 5-5)	Number (%) of responders by treatment group	TP, RP	Frequency counts and percentages
GAIS raw score as assessed by participant	Number (%) of each response category by treatment group	TP, RP	Frequency counts and percentages
Raw value and change from baseline in skin hydration; the median of multiple assessments per cheek per e-CRF visit will be calculated and the average of the medians of both cheeks will be used for the analysis	Summary by treatment group	CP, TP, RP	Continuous descriptive statistics
Composite responder status on ACSS and FACE-Q satisfaction with skin questionnaire	Number (%) of responders by treatment	CP, TP, RP	Frequency counts and percentages

Endpoint	Description	Analysis Period	Methodology
overall score	group		

Table 5-5 Global Aesthetic Improvement Scale

Score	Grade	Description
2	Much Improved	Marked improvement in appearance
1	Improved	Improvement in appearance, but a touch-up or retreatment is indicated
0	No Change	The appearance is essentially the same as the original condition
-1	Worse	The appearance is worse than the original condition
-2	Much Worse	The appearance is much worse than the original condition

5.6. Safety Analyses

The safety variables including AEs, injection site responses (ISRs), subject assessment of procedural pain, visual acuity, FACE-Q Recovery Early Life Impact questionnaire, confrontational visual fields, and ocular motility assessments will be analyzed using the safety population. Analyses of key safety variables for the Fitzpatrick safety cohort will be evaluated outside of the CSR analyses.

5.6.1. Extent of Exposure

Treatment exposure-related variables will be summarized for the VT and VRT populations. Study treatment exposure will be measured by volume injected at each treatment (Table 5-6). The number and percentage of participants for the study intervention volume injected will be tabulated by cheek at initial, touch-up, and repeat treatments as well as the combination of the initial and touch-up treatments.

Table 5-6 Exposure to Study Treatment

Endpoint	Description	Timing	Methodology
Volume injected • Left cheek • Right cheek • Total	Summary by treatment group, treatment (initial, touch-up, repeat, initial and touch-up combined), and side of face	Initial, Touch-up, Repeat, Initial and Touch-up combined	Continuous descriptive statistics

5.6.2. Administration of Study Treatment

Variables related to administration of treatment listed in Table 5-7 will be summarized for the VT population by treatment group and by side of the face at the initial and the touch-up treatments, and for the VRT population by side of the face at the repeat treatment.

Table 5-7 Administration of Study Treatment

Endpoint	Description	Timing	Methodology
Pre-treatment Anesthesia type • Ice • Topical	Summary by treatment group, treatment (initial, touch-up or repeat)	Initial, Touch-up, Repeat	Frequency counts and percentages
Pre-treatment anesthesia duration (minutes) • Anesthesia duration is computed as injection time minus start of anesthesia administration time. Summarize by treatment group, treatment, and anesthesia type.	Summary by treatment group, treatment (initial, touch-up or repeat)	Initial, Touch-up, Repeat	Continuous descriptive statistics
Treatment administration • Planes of injection • Average spacing of injection • Needle used • Number of needles used • Device/Needle problem or malfunction	Summary by treatment group, treatment (initial or touch-up), and side of face	Initial, Touch-up, Repeat	Frequency counts and percentages

5.6.3. Adverse Events

An AE will be considered a treatment emergent adverse event (TEAE) if the AE began or worsened (increased in severity or became serious) after first administration of VOLITE for the treatment group and after the date of randomization for the control group. A TESAE is defined as an SAE that is also a TEAE. Overall summary will be provided on a per-participant level for TEAEs, treatment-related TEAEs, TESAEs, deaths, and TEAEs leading to study intervention discontinuation.

If more than one event is coded to the same PT for the same participant, the participant will be counted only once for that PT using the greatest severity for the summarizations by severity and most related occurrence for the summarizations by relationship to study intervention. If the severity of a TEAE is missing, the maximum severity will be assigned to the event for the summarization by severity. The value will be displayed as missing in the data listing. If the relationship to the study intervention is missing for a TEAE, the event will be considered related to the study intervention for the summarization. The value will be displayed as missing in the data listing.

TEAEs will be summarized by treatment group for CP using the Safety population. TEAEs will also be summarized for TP and RP using the VT and VRT populations, respectively.

The number and percentage of participants with TEAEs and the events in the following AE categories will be summarized for the above populations as described in Table 5-8. For participants who received repeat treatment, their AEs reported during the first month in the initial treatment period will be summarized and presented in parallel with AEs reported during the repeat treatment period.

Summary tables will be provided for participants with TESAEs and participants with TEAEs leading to discontinuation if these occurred in 5 or more participants. Listings of all TEAEs, AESIs, TESAEs, TEAEs leading to discontinuation, and death will be presented.

Table 5-8 TEAE Summaries

Endpoint	Description	Timing	Methodology
Overall summary	Overall summary only for the following categories: • TEAEs • Treatment-related TEAEs • Treatment-related TEAEs at injection site • Treatment-related TEAEs not at injection site • TESAEs • Treatment-related TESAEs • Treatment-related TESAEs at injection site • Treatment-related TESAEs not at injection site • Discontinued due to TEAE • Deaths	CP, TP, RP	Frequency counts and percentages
TEAEs	• Overall summary and by SOC and PT • Overall summary and by SOC, PT, and severity	CP, TP, RP	Frequency counts and percentages
Treatment-related TEAEs	• Overall summary and by SOC and PT • Overall summary and by SOC, PT, and severity • Overall summary of duration, time to onset, and outcome by severity	CP, TP, RP	Frequency counts and percentages
TESAEs	Overall summary and by SOC and PT	CP, TP, RP	Frequency counts and percentages
TEAEs leading to discontinuation	Overall summary and by SOC and PT	CP, TP, RP	Frequency counts and percentages

5.6.3.1. Adverse Events of Special Interest

ISRs recorded in participant ISRs recorded in participant diaries after each treatment (initial, touch-up and repeat) will be summarized for that treatment, respectively. The diary date and time will be compared with the treatment injection ISRs recorded in participant diaries after each treatment (initial, touch-up and repeat) will be summarized for that treatment, respectively. The diary date and time will be compared with the treatment injection ISRs recorded in participant diaries after each treatment (initial, touch-up and repeat) will be summarized for that treatment, respectively. The diary date and time will be compared with the treatment injection Add analysis for adverse events of special interest. The list of adverse events of special interest can be defined in Section 6 or defined in this section if the list is not too lengthy.

5.6.4. Injection Site Response

ISRs recorded in participant diaries after each treatment (initial, touch-up or repeat) and the ongoing ISR e-CRF will be summarized. The diary date and time will be compared with the treatment injection date and time recorded in the database to determine the corresponding treatment (ie, initial, touch-up, or repeat) for the purpose of analysis. If there are multiple diary entries of the same treatment period for any day, then the worse severity and maximum duration

will be included in the summary for the corresponding symptom(s) analyzed. The descriptive statistics will be tabulated for the endpoints listed in Table 5-9 for the initial treatment, touch-up treatment, and repeat treatment periods by pre-defined symptoms.

Table 5-9 Injection Site Response Analyses

Endpoint	Description	Timing	Methodology
ISR severity	Maximum reported severity for 2 summaries listed below: • Up to 30 days after the treatment (initial, touch-up or repeat) based on diary data only • Beyond 30 days after the (initial, touch-up or repeat) treatment across the diary and ongoing ISR eCRF	Initial, Touch-up, Repeat	Frequency counts and percentages
ISR duration	Duration from first instance of the symptom to the last instance of the symptom within the treatment period for 2 summaries listed below: • Up to 30 days after the treatment (initial, touch-up or repeat): duration is derived as date of last ISR minus date of first ISR plus one based on the diary data between the date of corresponding treatment and 30 days after it on the participant level, regardless of the side of cheek. • Beyond 30 days after the (initial, touch-up or repeat) treatment: duration is calculated as the last minus the first ISR occurrence date plus one based on all data collected from diary and ongoing ISR eCRF.	Initial, Touch-up, Repeat	Frequency counts and percentages

Other symptoms of ISR entered in the e-diary by participants will be coded into medical terminologies by the medical safety physician. Other ISRs with "No", "None", or texts with a similar meaning will be coded as "n/a". If other ISRs are coded as one of the prespecified symptoms (ie., redness, pain after injection, tenderness to touch, firmness, lumps/bumps, bruising, itching, and discoloration), then the participant will be counted only once based on the maximum severity and duration across the pre-specified symptom entries and the coded terms. Other symptoms of ISR that were coded into the terms beyond the list of pre-specified symptoms will be summarized under "Other symptoms" in the summary tables for ISR. If a participant reported more than one non-prespecified terms of "other ISR", the participant will be counted once in the summary of "Other symptoms" for that treatment. The free texts entered by the participant, and the coded terms for "other symptoms" will be included in the data listing.

ISR day will be derived as ISR date – most recent treatment date + 1.

5.6.5. Procedural Pain

Participant assessment of procedural pain (pain during injection) on an 11-point scale ranging from 0 (no pain) to 10 (worst pain imaginable) after initial treatment will be summarized. The summary will be performed for initial treatment as described in Table 5-10.

Table 5-10 Procedural Pain Analyses

Endpoint	Description	Timing	Methodology
Procedural pain	Summary of pain scores as continuous scale	Initial	Continuous descriptive statistics

5.6.6. Other Safety Endpoints

Other safety endpoints include the line change on Snellen visual acuity, confrontation visual fields, ocular motility assessments, and the overall converted score of FACE-Q Recovery Early Life Impact questionnaire (see Section 6.5.5 and Section 6.5.6).

The number of line change based on Snellen visual acuity will be calculated using the formula below and rounded to the nearest integer. Baseline in the below formula is the pre-treatment value on or before the most recent treatment.

$$\text{Line change} = 10 \times [\log10 (d_{baseline}/20) - \log10 (d_{follow\text{-}up}/20)]$$

where $d_{baseline}$ = denominator of the Snellen equivalent unit at baseline,

$d_{follow\text{-}up}$ = denominator of the Snellen equivalent unit at follow-up visit

Line change of visual acuity, confrontation visual fields, and ocular motility assessments assessed by the TI (or designee) will be summarized by descriptive statistics. The overall converted score of FACE-Q Recovery Early Life Impact questionnaire calculated based on the conversion table will be summarized by descriptive statistics.

5.6.7. Vital Signs

Vital sign measurements, including blood pressure (systolic and diastolic, while participant is seated), pulse rate, and temperature will be presented by a data listing.

5.6.8. Pregnancy Test Analyses

Urine pregnancy test is taken at screening, prior to every treatment (initial, touch-up and repeat), and study exit. Participants with a positive result for the Safety Population throughout the study period will be presented by a data listing.

5.7. Other Analyses

5.7.1. Subgroup Analyses

Analysis of the primary effectiveness endpoint, ACSS responder status at Month 1, will be performed separately by the following subgroups based on the observed data:

- Baseline ACSS score: 2 and 3
- Fitzpatrick skin phototype: I/II, III/IV, and V/VI

- Volume injected: ≤ median and > median
- Injection plane/technique: microdepot intradermal injection vs. other injections
- Investigational site

The median total volume injected for the initial and touch-up treatments combined on both cheeks will be calculated to determine the cut-off for the subgroup listed above. Participants who received microdepot non-intradermal injections, non-microdepot intradermal, or non-microdepot non-intradermal injections for the initial or touch-up treatment are included in the subgroup of "other" injections.

5.8. Interim Analyses

No interim analysis is planned for this study.

6. Supporting Documentation

6.1. Appendix 1: List of Abbreviations

ACSS	Allergan Cheek Smoothness Scale
AE	adverse event
AFLS	Allergan Fine Lines Scale
AESI	Adverse Events of Special Interest
ATC	Anatomical Therapeutic Chemical
CI	confidence interval
CP	control period
eCRF	electronic case report form
EI	Evaluating Investigator
GAIS	Global Aesthetic Improvement Scale
ISR	injection site response
ITT	intent-to-treat
MedDRA	medical dictionary for regulatory activities
mITT	modified intent-to-treat
RP	repeat treatment period
SAE	serious adverse event
SAP	statistical analysis plan
SI	Le Système International d'Unités (International System of Units)
SOC	system organ class
TEAE	treatment-emergent adverse event
TESAE	treatment-emergent serious adverse event
TP	treated period
VRT	VOLITE repeat treatment population
VT	VOLITE treated population
WHO	World Health Organization

6.2. Appendix 2: Changes to SAP Version 1 Analyses

The following are changes to version 1 of SAP:

1. The naming of the analysis population for the sensitivity analysis of primary endpoint, ACSS responder status at Month 1 was changed from "Completer Population" to "Observed Primary Endpoint" in Section 4. The definition of this population refers to the completion of the primary timepoint visit (ie., Month 1 of CP). This naming change is aimed to avoid potential confusion with study completion.
2. The wordings of "overall converted score" were specified for the analyses of FACE-Q Satisfaction with Skin, FACE-Q Appraisal of Lines, and FACE-Q Recovery Early Life Impact in Sections 4, 5.4, 5.5 and 5.6.5 to enhance clarity and consistency with Appendix 6.5.
3. The cut-off for the of FACE-Q Satisfaction with Skin as one of the definitions for Fitzpatrick Safety Cohort was changed from 39 for the overall raw score to 69 for the overall converted score in Table 4-1.
4. The definition of "baseline" for the effectiveness and safety variables in Section 5.1 was changed to "the last non-missing assessment prior to the latter of randomization or first treatment in the control period" due to possibility of participants who were mis-treated (ie., either randomized to Volite but was not treated or randomized to Control but received Volite)
5. The multiple imputation for the primary effectiveness analysis described in Section 5.3.2 was revised to (1) include the baseline ACSS score and age in the model based on the correlation with the primary endpoint to be imputed (ie., ACSS score at Month 1 of CP) and (2) number of imputed dataset is increased from 5 to 30 to reduce variability and increase the efficiency of estimates
6. The derivation for skin hydration and analyses of following variables were added to other effectiveness analyses in Section 5.5:
    a. raw value and change from baseline in ACSS
    b. raw value and change from baseline in AFLS
    c. item scores and aggregated categories for FACE-Q Satisfaction with Skin
    d. item scores and aggregated categories for FACE-Q Appraisal of Lines
7. The analysis of ISR in Section 5.6.3 was revised to include: (1) ISR by maximum severity for summaries up to 30 days and beyond 30 days after treatment, (2) analysis of "other symptoms" based on the coded terms assigned by the Medical Safety Physician

8. The baseline for the analysis of visual acuity in Section 5.6.5 was specified as the pre-treatment value on or before the most recent treatment for each visit analyzed
9. A data listing to tabulate the vital sign data collected during the study is added to Section 5.6.6
10. A data listing to tabulate the positive pregnancy test during the study is added to Section 5.6.7
11. The subgroup analyses by injection technique/plane (microdepot intradermal injection vs. other injections) as requested by the FDA and by investigator site were added to Section 5.7.1
12. The inclusion of safety data collected at the unscheduled visits in the data listing was added to Section 6.4.1.2
13. The imputation algorithms for the start and end dates of medication were added to Section 6.4.2, 6.4.2.3, and 6.4.2.4 in order to determine the classification of prior vs. concomitant mediations for the data listing.
14. The imputation for the missing items of FACE-Q Satisfaction with Skin, FACE-Q Appraisal of Lines, and FACE-Q Recovery Early Life Impact were added to Section 6.5.2, 6.5.4, and 6.5.6, respectively

6.3. Appendix 3: Supporting Study Information

6.3.1. Demographics

Demographic parameters (age [years]; sex; race; ethnicity) will be summarized descriptively by treatment group for the mITT populations. Age (years) were calculated relative to informed consent date.

6.3.2. Baseline and Disease Characteristics

Baseline characteristics listed below will be summarized descriptively in total and by treatment group for the mITT populations as follows:

- Weight (kg), height (cm), and BMI (kg/m2)
- Sun exposure (hours per day)
- Fitzpatrick skin phototype (each phototype, and by phototype groups [I and II, III and IV, V and VI])
- Smoking history (status, tobacco product, frequency, and duration in months)

6.3.3. Protocol Deviations

Significant protocol deviations will be identified. Unique participants reporting significant protocol deviations will be summarized in total and by treatment group for all randomized participants as described in Table 6-1.

Listing of significant protocol deviations will be provided.

Table 6-1 Protocol Deviation Summary

Endpoint	Description	Timing	Methodology
Significant protocol deviations	Number (%) of participants with significant protocol deviation will be summarized (All randomized)	During study period	Categorical descriptive statistics

6.3.4. Medical History

The medical and surgical history will be tabulated in data listing.

6.3.5. Prior/Concomitant Medications

Prior medication is defined as any medications taken prior to the latter of randomization date or first treatment date in the control period. Concomitant medication is defined as any medication taken on or after the latter of randomization date or first treatment date in the control period. The prior and concomitant medications will be tabulated in the data listing.

6.4. Data Handling Convention

6.4.1. Analysis Window

6.4.1.1. Effectiveness

Table 6-2, Table 6-3, and Table 6-4 below present the timepoints assigned for analyses and the corresponding range of study days for all the scheduled and unscheduled visits with complete dates. If a scheduled visit with incomplete date is available with no other visits with complete date during the visit window, then the visit with incomplete date may be used for analysis and the nominal visit will be used as the visit window (eg, if the only assessment collected for Month 2 visit window is on a Month 2 eCRF with incomplete date, then those data will be used for the Month 2 assessments).

If multiple assessments were taken within an analysis window, the assessment obtained on the day closest to the target day will be used; in the case of a tie, the assessment obtained on the later day will be used in the analysis.

Analysis visit windows for effectiveness endpoints are defined as follows:

If analysis date ≥ reference date, then
Analysis day = analysis date – reference date + 1

If analysis date < reference date, then
Analysis day = analysis date – reference date

Table 6-2 Effectiveness Analysis Visit Definitions for Treatment Group and Control Group during Treated Period

Scheduled Visit for Effectiveness Measure	Target Day of the Visit	Analysis Visit Window
Screening[a]	N/A	Screening visit; no more than 30 days prior to randomization
Baseline	N/A	Randomization/Initial Treatment visit
Last Treatment[b]	Day 1 of Last Treatment	Day 1
Month 1	Day 31 Post Last Treatment	Day 2 to Day 46
Month 2	Day 61 Post Last Treatment	Day 47 to Day 91
Month 4	Day 121 Post Last Treatment	Day 92 to Day 151
Month 6	Day 181 Post Last Treatment	Day 152 to Repeat Treatment Date (if applicable) or Study Exit Date, whichever is earlier

[a] Participants may have screening and randomization on the same day. In such cases, only randomization visit is relevant
[b] The last treatment refers to the latter of initial treatment or touch-up treatment (if applicable)

Table 6-3 Effectiveness Analysis Visit Definitions for Control Group during Control Period

Scheduled Visit	Target Day of the Visit	Analysis Visit Window
Randomization Day	Day 1	N/A
Month 1	Day 31	Day 2 to Optional Treatment Date or Study Exit Date, whichever is earlier.

Table 6-4 Effectiveness Analysis Visit Definitions for Treatment Group during Repeat Treatment Period

Scheduled Visit for Effectiveness Measure	Target Day of the Visit	Analysis Visit Window
Repeat Treatment[a]	Day 1 Repeat Treatment	Day of the Repeat Treatment
Month 1 Repeat	Day 31 Post Repeat Treatment	Day 2 to Day 76 Post Repeat Treatment
Month 4 Repeat	Day 121 Post Repeat Treatment	≥ Day 77 Post Repeat Treatment

[a] Not all participants will receive repeat treatment

6.4.1.2. Safety

The safety data will be analyzed based on nominal visits recorded on eCRF. The safety data collected at the unscheduled visits will be included in the data listings only.

6.4.2. Missing Date Imputation

Missing date will be imputed for TEAEs and medications. The missing AE dates will be imputed with year, month, and day values based on the corresponding scenarios in Table 6-5 and algorithms described in Sections 6.4.2.1 and 6.4.2.2. If the AE stop date is complete and the imputed AE start date is after the stop date, the AE start date will be re-imputed using the stop date. If the imputed AE stop date is before the start date (imputed or non-imputed start date), the start date will be the imputed stop date.

The missing medication start and stop dates will be imputed based on the algorithms described in Sections 6.4.2.3 and 6.4.2.4. When the medication start date and stop date are both incomplete for a participant, the start date will be imputed first. If the medication stop date is complete and the imputed start date is after the stop date, the start date will be imputed using the stop date. If the imputed medication stop date is before the start date (imputed or non-imputed start date), the start date will be the imputed stop date.

Table 6-5 Imputation Scenarios

Scenario	Complete			Imputable
	Year	Month	Day	
1	Yes	Yes	Yes	N/A
2	Yes	Yes	—	Yes
3	Yes	—	Yes	No[a]
4	Yes	—	—	Yes
5	—	Yes	Yes	No[a]
6	—	Yes	—	No[a]
7	—	—	Yes	No[a]
8	—	—	—	Yes

[a] Not allowed per database design.

6.4.2.1. Missing/Incomplete AE Start Date

For scenario 2 from Table 6-5 (if day is missing but month and year are available), then the imputed day will be the first day of the month or the date of first study treatment (which will be the date of randomization for control group) if they have the same month and year, whichever is later (because TEAE onset is not expected prior to administration of study treatment).

For scenario 4 (if day and month are missing but year is available), then the imputed day and month will be 01 Jan or the date of first study treatment (or date of randomization for control group) if they have the same year.

For scenario 8 (if day, month and year are all missing), impute start date as the latter of randomization date or first study treatment date.

6.4.2.2. Missing/Incomplete AE End Date

For scenario 2 (if day is missing but month and year are available), then the imputed day will be the last day of the month or the study exit date if they have the same month and year.

For scenario 4 (if day and month are missing but year is available), then the imputed day and month will be 31 Dec., or the study exit date if they have the same year.

For scenario 8, (if day, month and year are all missing), then the imputed date will be the latest possible date on or before study exit date.

6.4.2.3. Missing/Incomplete Medication Start Date

If day is missing but month and year are available for the medication start date (e.g., Jul 2019), the incomplete date will be imputed by the first day of the month (e.g., 01 Jul 2019).

If day and month of the medication start date are missing (e.g., 2019), the incomplete date will be imputed as the first day of the year (e.g., 01 Jan 2019).

6.4.2.4. Missing/Incomplete Medication End Date

If the e-CRF question, “is medication still ongoing” was not responded “Yes”, then the following algorithms will be implemented to impute the missing/incomplete medication end date.

If day is missing but month and year are available for the medication end date (e.g., Jul 2019), the incomplete date will be imputed by using the last day of the month (e.g., 31 Jul 2019).

If day and month of the medication end date are missing (e.g., 2019), the incomplete date will be imputed as the last day of the year (e.g., 31 Dec 2019).

However, in both situations described above, an upper limit of the subject's death date (if applicable) will be used, such that if the imputed date is after the subject's death date, the imputed date will be replaced with the subject's death date.

6.5. FACE-Q Questionnaires and Conversion Tables

6.5.1. FACE-Q™ – Satisfaction with Skin

For each question, circle only one answer. With your facial skin (complexion) in mind, in the past week, how satisfied or dissatisfied have you been with:

	Very Dissatisfied	Somewhat Dissatisfied	Somewhat Satisfied	Very Satisfied
a. How your facial skin looks at the end of your day?	1	2	3	4
b. How healthy your facial skin looks?	1	2	3	4
c. How attractive your facial skin makes you look?	1	2	3	4
d. How smooth your facial skin looks?	1	2	3	4
e. How clear your facial skin (complexion) looks?	1	2	3	4
f. How refreshed your facial skin makes you look?	1	2	3	4
g. How hydrated your facial skin looks?	1	2	3	4
h. How your facial skin looks when you first wake up?	1	2	3	4
i. How radiant your facial skin looks?	1	2	3	4
j. How the tone (color) of your facial skin looks?	1	2	3	4
k. How your pores look?	1	2	3	4
l. How even-colored your facial skin looks?	1	2	3	4

Note to Investigators: This scale can be used independently of the other scales.

6.5.2. FACE-Q™ – Satisfaction with Skin Conversion Table

Instructions:

For items with missing data (which includes more than 1 response was selected, non-applicable (N/A) was selected or a question was skipped), insert the unrounded mean of the completed items into the total sum score. If less than 50% of the questions have been answered (ie., number of missing items is 7 or more), then the overall score will be missing. The summed score including the imputation of missing items is rounded to the nearest integer and converted to the Rasch transformed score using the conversion table below. Higher scores reflect a better outcome. The converted score ranges from 0 (worst) to 100 (best).

SUM SCORE	EQUIVALENT RASCH TRANSFORMED SCORE (0-100)
12	0
13	3
14	9
15	14
16	18
17	21
18	24
19	26
20	29
21	32
22	34
23	36
24	39
25	41
26	43
27	45
28	47
29	49
30	51
31	53
32	55
33	57
34	59
35	61
36	63
37	65
38	67
39	69
40	72
41	74
42	76

SUM SCORE	EQUIVALENT RASCH TRANSFORMED SCORE (0-100)
43	79
44	81
45	84
46	88
47	93
48	100

6.5.3. FACE-Q™ – Appraisal of Lines: Overall

For each question, circle only one answer. With your entire face in mind, in the past week, how much have you been bothered by:

	Not at all	A little	Moderately	Extremely
a. How deep the lines on your face are?	1	2	3	4
b. Lines you see in photos?	1	2	3	4
c. Lines when your face is relaxed (still)?	1	2	3	4
d. Lines when you smile?	1	2	3	4
e. The number of lines on your face?	1	2	3	4
f. How noticeable the lines on your face are?	1	2	3	4
g. Lines when you frown?	1	2	3	4
h. How old the lines on your face make you look?	1	2	3	4
i. Lines you see when you look in the mirror?	1	2	3	4
j. Lines you see under bright lights?	1	2	3	4

Note to Investigators: This scale can be used independently of the other scales.

6.5.4. FACE-Q™ – Appraisal of Lines: Overall Conversion Table

Instructions: Ensure the data are rescored as follows: "Not at all" = 4; "A little" = 3; "Moderately" = 2; "Extremely" = 1. For items with missing data (ie., more than 1 response was selected, N/A or a question was skipped), insert the unrounded mean of the completed items into the total sum score. If less than 50% of the questions have been answered (ie., number of missing items is 6 or more), then the overall score will be missing. The summed score is rounded to the nearest integer and converted to the Rasch transformed score using the conversion table below. Higher scores reflect a better outcome. The converted score ranges from 0 (worst) to 100 (best).

SUM SCORE	EQUIVALENT RASCH TRANSFORMED SCORE (0-100)
10	0
11	7
12	13
13	17
14	20
15	24
16	27
17	29
18	32
19	35
20	38
21	40
22	43
23	45
24	48
25	50
26	52
27	55
28	57
29	60
30	63
31	65
32	68
33	71
34	74
35	76
36	80
37	83
38	87
39	93
40	100

6.5.5. FACE-Q™ – Early Life Impact of Treatment

For each question, circle only one answer. These questions ask about recovery from your surgery or procedure. With your most recent facial surgery or procedure in mind, in the past 2 days, how often have you:

	Not at all	Some of the time	Most of the time
a. Felt regret about the surgery or procedure?	1	2	3
b. Felt more anxious than usual?	1	2	3
c. Had trouble sleeping?	1	2	3
d. Wondered if the surgery or procedure was worthwhile?	1	2	3
e. Felt more tired than usual?	1	2	3
f. Avoided certain head movements (e.g. bending your head down)?	1	2	3
g. Not done your usual day-to-day activities (e.g. going to work, running errands)?	1	2	3
h. Avoided certain facial movements (e.g. laughing, squinting)?	1	2	3
i. Had difficulty drinking?	1	2	3
j. Had difficulty eating?	1	2	3
k. Avoided social situations?	1	2	3
l. Avoided intimacy (e.g. kissing or hugging)?	1	2	3

Note to Investigators: This scale can be used independently of the other scales.

6.5.6. FACE-Q™ – Early Life Impact of Treatment Conversion Table

Instructions: Ensure the data are rescored as follows: "Not at all" = 3; "Some of the time" = 2; "Most of the time" = 1. Higher scores reflect a better outcome. For items with missing data (which includes more than 1 response was selected, non-applicable (N/A) was selected or a question was skipped), insert the unrounded mean of the completed items into the total sum score. If less than 50% of the questions have been answered (ie., number of missing items is 7 or more), then the overall score will be missing. The summed score including the imputation of missing items is to be rounded to the nearest integer and converted to the Rasch transformed score using the conversion table below. Higher scores reflect a better outcome. The converted score ranges from 0 (worst) to 100 (best).

SUM SCORE	EQUIVALENT RASCH TRANSFORMED SCORE (0-100)
12	0
13	7
14	16
15	22
16	26
17	30
18	34
19	37
20	40
21	43
22	46
23	49
24	51
25	54
26	56
27	58
28	61
29	64
30	66
31	70
32	73
33	77
34	82
35	90
36	100

7. References

Pusic AL, Klassen AF, Scott AM, Cano SJ. Development and psychometric evaluation of the FACE-Q satisfaction with appearance scale: a new patient-reported outcome instrument for facial aesthetics patients. Clin Plast Surg. 2013;40(2):249-260.