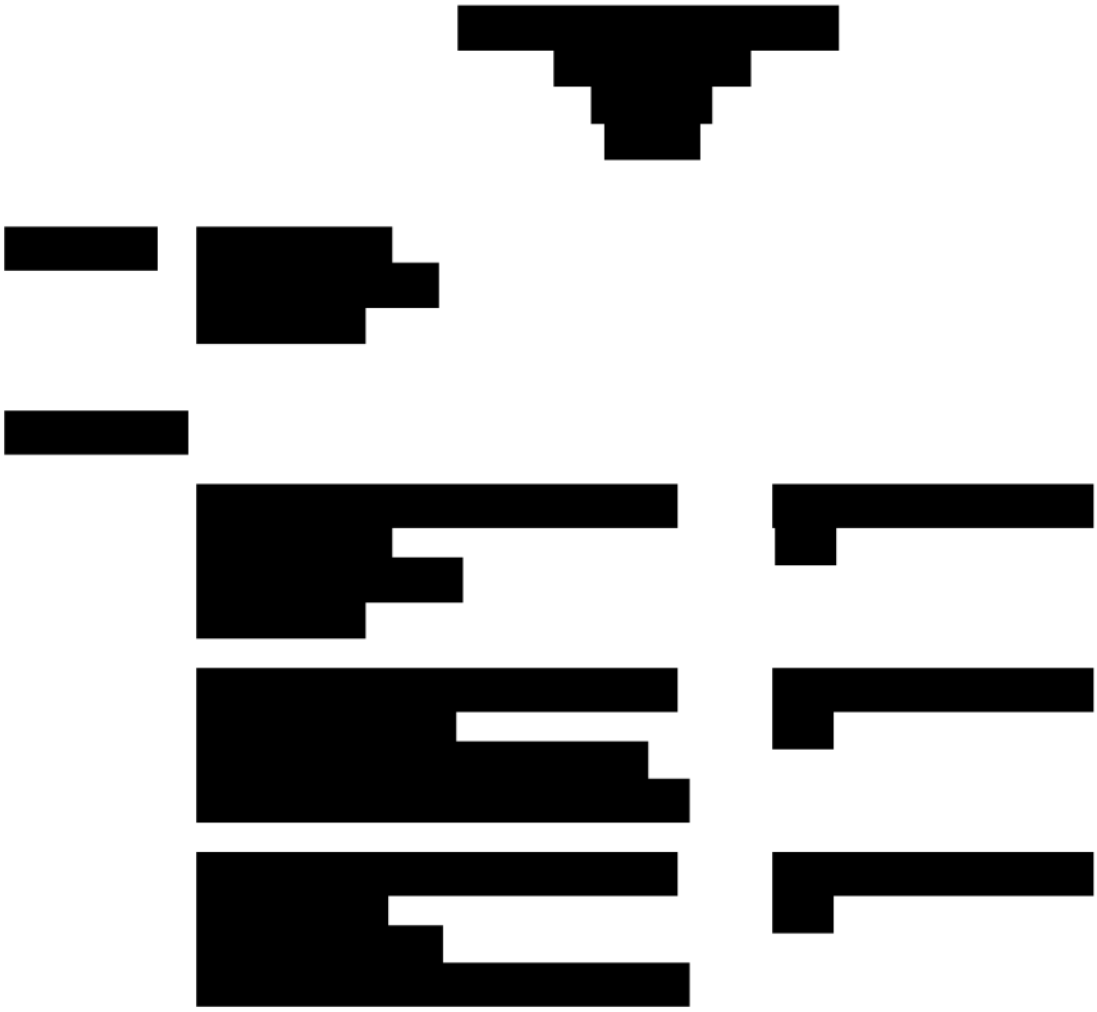
STATISTICAL ANALYSIS PLAN

Protocol PRO 2018-03

Version 1.0
March 6, 2019

A Multicenter, Open-Label Retreatment Study of the Safety and Effectiveness of PN40082 for Lip Augmentation

Prollenium Medical Technologies Inc.



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Statistical Analysis Plan

1 Purpose of Statistical Analysis Plan

The purpose of the statistical analysis plan is to describe in detail all the data, statistical methods, and summary tables required to implement the statistical analysis of Clinical Study Protocol PRO 2018-03 (Section 8 in the study protocol version 2.0, dated November 13, 2018).

2 Study Objectives

To evaluate the safety and efficacy of retreatment with PN40082 for lip augmentation.

3 Study Design and Sample Size Determination

3.1 Study Design

For the purpose of exploring the above objectives, the study will be conducted as a multicenter, open-label clinical study of retreatment with PN40082 of subjects seeking lip augmentation who initially received treatment with either PN40082 or Restylane Silk in the prior PRO 2018-02 study. Subjects meeting the inclusion/exclusion criteria will receive a single additional treatment with PN40082.

Visits will occur at:
- Visit 1 / Day 1 – baseline and treatment. This is the same visit as Visit 5 (Day 168) of Protocol PRO 2018-02.
- Visit 2 / Day 28 (±2 days) / Month 1 – interim visit
- Visit 3 / Day 56 (±4 days) / Month 2 – End of Study (EOS) Visit.

Telephone contacts for safety follow-up will occur at:
- Day 3 (±2 days) - Safety follow-up telephone call
- Day 14 (±2 days) – Safety follow-up telephone call
- Day 168 (±7 days) / Month 6 – Safety follow-up telephone call

Evaluations include:
- Lip Fullness Grading Scale (LFGS) (Overall lip fullness considering both lips together, fullness of the upper lip and fullness of the lower lip)
- Perioral lines at rest severity scale (POL) (Overall perioral lines at rest severity considering both lips together, perioral lines at rest severity of the upper lip and perioral lines at rest severity of the lower lip)
- Patient Global Aesthetic Improvement (pGAI)
- Investigator Global Aesthetic Improvement (iGAI)
- Swelling Assessment
- Subject Satisfaction with Lips Assessment (using VAS)

Safety will be assessed by monitoring adverse events (AEs) and concomitant medications at all study visits. Other Safety evaluations include lip function, lip sensation, lip texture, lip firmness, lip symmetry and lip movement/function. Other evaluations include Investigator Ease of Use Assessment.

3.2 Sample Size Determination

The maximum sample size was determined by the number of subjects who completed the prior PRO 2018-02 study and elected retreatment with PN40082

4 Populations To Be Analyzed

All retreated subjects will be included in the analysis.

5 Planned Analyses

5.1 Methodological Considerations

All the data points for the retreatment period will be presented in subject data listings. No inferential statistical analyses will be performed. SAS software (version 9.4 or higher) will be used for all data analyses and tabulations.

Efficacy and safety data will be summarized overall and also broken down by the treatment arm in PRO 2018-02.

5.2 Handling of Dropouts or Missing Data

All summaries will be generated using the available data without imputation for the missing values.

5.3 Demographics and Baseline Characteristics

Demographic and baseline characteristic variables (including age, sex, race, ethnicity, and Fitzpatrick skin type) will be tabulated using descriptive statistics. For each continuous variable, the summary will include the mean, standard deviation (SD), median, minimum and maximum. For each categorical variable, the summary will include frequencies and percentages.

5.4 Subject Accountability

A summary of subject disposition will be provided for all subjects descriptively, including reason for discontinuation.

5.5 Efficacy Variables

Key efficacy assessments include the following:

- LFGS: 0 = very thin, 1 = thin, 2 = moderately thick, 3 = thick, 4 = full
- POL: 0 = None (a mouth with no perioral lines), 1 = Mild (a mouth with a few shallow perioral lines), 2 = Moderate (a mouth with some moderate lines), 3 = Severe (a mouth with many deep lines or crevices)
- Subject Satisfaction with Lips using a visual analog scale (VAS) on a 100-mm scale from 0 = Very Unsatisfied to 100 = Very Satisfied
- Patient Global Aesthetic Improvement (pGAI) Score: 1=Worse, 2=No change, 3=Improved, 4=Much improved, 5=Very much improved
- Investigator Global Aesthetic Improvement (iGAI) Score: 1=Worse, 2=No change, 3=Improved, 4=Much improved, 5=Very much improved
- Swelling Assessment: 0 = None, 1 = Minimal, 2 = Mild, 3 = Moderate, 4 = Severe

5.5.1 Efficacy Analysis

For LFGS and POL, actual values will be summarized by visit. Change from baseline in this study and change from baseline in the prior controlled study (PRO 2018-02) will also be summarized at Visit 2/Month 1 and Visit 3/Month 2. Summary statistics include mean, SD, minimum, median, and maximum.

Other efficacy variables including pGAI, iGAI, and Swelling Assessment will also be tabulated by visit using frequencies and percentages.

5.6 Safety Variables

Key safety variables include incidence rate of treatment-emergent adverse events (TEAEs) and the exposure to the study product, as well as Investigator Ease of Use Assessment, lip function, lip sensation, lip texture, lip firmness, lip symmetry, and lip movement/function.

5.6.1 Adverse Events

All adverse events (AEs) occurring during the study will be recorded and coded in the Medical Dictionary for Regulatory Activities (MedDRA), version 20 or higher. TEAEs are defined as events that appear subsequent to the open-label injection or that were present prior to the open-label injection but worsened in intensity after the open-label injection.

TEAEs (those related to vascular injections/Visual events, separate from those that were not related to vascular injections/Visual events) for the retreated subjects will be summarized grouped by the number of injections that were received of PN40082, or Restylane Silk during the prior controlled study (PRO 2018-02). Frequency and percent of subjects reporting TEAEs of injection site will be tabulated by preferred terms, and further by severity and relationship to study device. In summaries of severity and relationship, subjects who reported more than one event in a treatment arm that are mapped to the same preferred term will be counted only once in that treatment arm under the strongest severity and relationship, respectively.

TEAEs related to vascular injections/Visual events will also be tabulated by subject Fitzpatrick Skin Type (I-III vs. IV-VI), each Fitzpatrick Skin Type individually and by number of injections subjects received.

Treatment-Emergent Serious Adverse Events (TESAEs) and TEAEs that led to treatment interruption or discontinuation will be presented in data listings.

5.6.2 Exposure to PN40082

Amount of syringe used for open-label retreatment will be summarized using descriptive statistics (mean, SD, minimum, median, maximum) at Visit 1 for all retreated subjects.

5.6.3 Other Variables

<u>Investigator Ease of Use Assessment</u>

Overall ease of use of the device will be evaluated by the Treating Investigator using the numerical rating scale (NRS) from 0 being not easy to 10 being most easy at Visit 1/Day. It will be summarized for all retreated subjects descriptively with mean, SD, minimum, median, and maximum.

<u>Lip Evaluations</u>

Lip function, lip sensation, lip texture, lip firmness, lip symmetry, and lip movement/function will be evaluated by the Blinded Evaluating Investigator at each visit. These variables will be summarized using frequency and percent of subjects by categories of incidence.

Concomitant Medications

Concomitant medications will be coded using the World Health Organization (WHO) Drug Dictionary, Version March 2013 or later, and will be presented in data listings.

6 Tables and Listings

The following is an example of tables and listings that will be included in the clinical study report. Tables and listings may be modified as needed during the data analyses.

7 Appendices

7.1 Handling of Missing or Incomplete Dates for Adverse Events and Concomitant Medications

Adverse Events

Handling of partial dates is only considered for the start date. An adverse event with a partial start date is considered treatment emergent if:

- only the day is missing and the start month/year is the same or after the month/year of the first injection
- the day and month are missing and the start year is the same or greater than the year of the first injection date
- the start date is completely missing

Concomitant Medications

Handling of partial dates is only considered for the stop date. A medication with a partial stop date is considered concomitant if:

- only the day is missing and the stop month/year is the same or after the month/year of the first injection
- the day and month are missing and the stop year is the same or greater than the year of the first injection date
- the stop date is completely missing or the medication is ongoing.

7.2 Summary of Assessments

Visit Number (Month)	**Visit 1[a]**	**Phone Contacts**	**Visit 2 (Mo 1)**	**Visit 3 (Mo 2)**	**Phone Contact (Mo 6)**	**Unsched Visit**
Scheduled Day(s)	**Day 1**	**Day 3 & Day 14**	**Day 28**	**Day 56**	**Day 168**	
Scheduling Window	**± 7 days**	**± 2 days**	**± 2 days**	**± 4 days**	**± 7 days**	
Informed consent	X					
Medical history/ demographics	X[b]					
Vital Signs	X					
Vision evaluations (Snellen visual acuity, confrontational visual fields, ocular motility)[c]	X		X	X		X[d]
Concomitant medication/ Treatment	X	X	X	X	X	X
Inclusion/exclusion criteria review	X					
Urine pregnancy test[e]	X					
Lip Fullness Grading Scale (LFGS) (overall, upper lip, and lower lip)	X		X	X		X[d]
Perioral lines at rest severity scale (POL) (overall, upper lip, and lower lip)	X		X	X		X[d]
Treatment with PN40082	X					
Investigator Ease of Use Assessment	X					
Patient GAI (pGAI)	X		X	X		X[d]
Swelling Assessment	X		X	X		X[d]
Investigator GAI (iGAI)	X		X	X		X[d]
Subject Satisfaction with Lips	X		X	X		X[d]
Lip function	X[f]		X	X		X[d]
Lip sensation	X[f]		X	X		X[d]
Lip texture	X[f]		X	X		X[d]
Lip firmness	X[f]		X	X		X[d]
Lip symmetry	X[f]		X	X		X[d]
Lip movement/function	X[f]		X	X		X[d]
Adverse event assessment	X	X	X	X	X	X
Subject Diary	Dispense		Collect			

Note: The timing of each visit is relative to Day 1, which is defined as the day the subject is treated.

a. This is also Visit 5 of Protocol PRO 2018-02 and assessments performed at that visit do not need to be repeated.
b. To be updated if/as needed for changes since Visit 1 of PRO 2018-02.
c. To be performed prior to any treatment and repeated 30 minutes following any treatment and all follow-up visits.
d. If/as needed
e. For women of childbearing potential, to be completed prior to enrollment.
f. To be performed prior to injections

Summary Tables

Table 14.1.2 – Subject Discontinuations by Reason for All Retreated Subjects

	PRO 2018-02 PN40082	PRO 2018-02 Restylane Silk	Total
Subjects Who Received Open-Label Treatment	0	0	0
Number Completed Study	0 (0%)	0 (0%)	0 (0%)
Total Discontinued	0 (0%)	0 (0%)	0 (0%)
Reason Discontinued			
-- Subject or legal representative withdrew consent	0 (0%)	0 (0%)	0 (0%)
-- Significant protocol violation	0 (0%)	0 (0%)	0 (0%)
-- Subject became pregnant	0 (0%)	0 (0%)	0 (0%)
-- An AE occurs for which the subject or the investigator determines that it is in the subject's best interest to be discontinued	0 (0%)	0 (0%)	0 (0%)
-- Lost to follow-up	0 (0%)	0 (0%)	0 (0%)
-- Investigator discretion	0 (0%)	0 (0%)	0 (0%)
-- Other	0 (0%)	0 (0%)	0 (0%)

Source: Listing 16.2.1.1
O:\Studies\Prollenium\SYM 2018-03\Biometrics\Programs\Tables\xxx.sas ran on Month Day, Year at hh:mm on data from Month, Day, Year.

Table 14.1.5 – Demographic Characteristics for Retreated Subjects

Parameter	Category	PRO 2018-02 PN40082 (N=xx)	PRO 2018-02 Restylane Silk (N=xx)	Total (N=xx)
Gender	Female	0 (0%)	0 (0%)	0 (0%)
	Male	0 (0%)	0 (0%)	0 (0%)
Ethnicity	Hispanic or Latino	0 (0%)	0 (0%)	0 (0%)
	Not Hispanic or Latino	0 (0%)	0 (0%)	0 (0%)
	Not Willing to Provide	0 (0%)	0 (0%)	0 (0%)
Race	White	0 (0%)	0 (0%)	0 (0%)
	Asian	0 (0%)	0 (0%)	0 (0%)
	Native Hawaiian or Other Pacific-Islander	0 (0%)	0 (0%)	0 (0%)
	Black or African American	0 (0%)	0 (0%)	0 (0%)
	American Indian or Alaska Native	0 (0%)	0 (0%)	0 (0%)
	Other	0 (0%)	0 (0%)	0 (0%)
	Mixed*	0 (0%)	0 (0%)	0 (0%)
Age (years)	N	0	0	0
	Mean ± SD	00.0 ± 00.00	00.0 ± 00.00	00.0 ± 00.00
	Median	0.0	0.0	0.0
	Min, Max	0, 0	0, 0	0, 0
Age Groups	18 to < 40	0 (0%)	0 (0%)	0 (0%)
	40 to < 64	0 (0%)	0 (0%)	0 (0%)
	64 to <75	0 (0%)	0 (0%)	0 (0%)
	>= 75	0 (0%)	0 (0%)	0 (0%)
Body Mass Index (BMI)**	N	0	0	0
	Mean ± SD	00.0 ± 00.00	00.0 ± 00.00	00.0 ± 00.00
	Median	0.0	0.0	0.0
	Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0

Parameter	Category	PRO 2018-02 PN40082 (N=xx)	PRO 2018-02 Restylane Silk (N=xx)	Total (N=xx)
Fitzpatrick Skin Type	I	0 (0%)	0 (0%)	0 (0%)
	II	0 (0%)	0 (0%)	0 (0%)
	III	0 (0%)	0 (0%)	0 (0%)
	IV	0 (0%)	0 (0%)	0 (0%)
	V	0 (0%)	0 (0%)	0 (0%)
	VI	0 (0%)	0 (0%)	0 (0%)

*Subjects who reported more than one race are categorized as Mixed race.
** BMI = weight (lbs) / height² (in) x 703
Source: Listing 16.2.4.1, 16.2.4.6
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Table 14.2.1 – Efficacy: Change from Baseline in Overall Lip Fullness Grading Scale (LFGS) at Visit 2/Month 1 and Visit 3/Month 2

Study Visit	Category	Statistics	PRO 2018-02 PN40082	PRO 2018-02 Restylane Silk	Total
Visit 1/Day 1 PRO 2018-02	Actual Value	N	0	0	0
		Mean ± SD	0.0 ± 0.00	0.0 ± 0.00	0.0 ± 0.00
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
Visit 1/Day 1 Retreatment	Actual Value	N	0	0	0
		Mean ± SD	0.0 ± 0.00	0.0 ± 0.00	0.0 ± 0.00
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
Visit 2/Month 1	Actual Value				
	…				
	Change from Visit 1 PRO 2018-02				
	…				
	Change from Visit 1 Retreatment				
	…				
Visit 3/Month 2	…				

LFGS: 0=Very Thin Lips, 1=Thin Lips, 2=Moderately Thick Lips, 3=Thick Lips, 4=Full Lips.
Source: Listing 16.2.6.1
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Note:

Table 14.2.1 will be used as the shell for the following table:

Table 14.2.2 – Efficacy: Change from Baseline in Overall Perioral Lines at Rest (POL) Severity Scale at Visit 2/Month 1 and Visit 3/Month 2

With first footnote changed to the following:

POL severity: 0=None, 1=Mild, 2=Moderate, 3=Severe.

Table 14.2.3 – Efficacy: Patient Global Aesthetic Improvement (pGAI) by Visit

Study Visit	Category	PRO 2018-02 PN40082	PRO 2018-02 Restylane Silk	Total
Visit 1/Day 1 Retreatment	N	0	0	0
	1 = Worse	0 (0%)	0 (0%)	0 (0%)
	2 = No Change	0 (0%)	0 (0%)	0 (0%)
	3 = Improved	0 (0%)	0 (0%)	0 (0%)
	4 = Much Improved	0 (0%)	0 (0%)	0 (0%)
	5 = Very Much Improved	0 (0%)	0 (0%)	0 (0%)
Visit 2/Month 1	…			
Visit 3/Month 2	…			

Source: Listing 16.2.6.2
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Note:

Table 14.2.3 will be used as the shell for the following table:

Table 14.2.4 – Efficacy: Investigator Global Aesthetic Improvement (iGAI) by Visit

Table 14.2.5 – Efficacy: Swelling Assessment by Visit

Study Visit	Category	PRO 2018-02 PN40082	PRO 2018-02 Restylane Silk	Total
Visit 1/Day 1 Retreatment	N	0	0	0
	0 = None	0 (0%)	0 (0%)	0 (0%)
	1 = Minimal	0 (0%)	0 (0%)	0 (0%)
	2 = Mild	0 (0%)	0 (0%)	0 (0%)
	3 = Moderate	0 (0%)	0 (0%)	0 (0%)
	4 = Severe	0 (0%)	0 (0%)	0 (0%)
Visit 2/Month 1	…			
Visit 3/Month 2	…			

Source: Listing 16.2.6.2
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Table 14.2.6 – Efficacy: Subject Satisfaction with Lips VAS by Visit

Study Visit	Statistics	PRO 2018-02 PN40082	PRO 2018-02 Restylane Silk	Total
Visit 1/Day 1 Retreatment	N	0	0	0
	Mean ± SD	0.0 ± 0.00	0.0 ± 0.00	0.0 ± 0.00
	Median	0.0	0.0	0.0
	Min, Max	0, 0	0, 0	0, 0
Visit 2/Month 1	…			
Visit 3/Month 2	…			

Source: Listing 16.2.6.2
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Table 14.3.1.1 – Exposure to Study Product and Investigator Ease of Use Assessment (Upper Lips) at Visit 1/Day 1 Retreatment

	Statistics	PRO 2018-02 PN40082	PRO 2018-02 Restylane Silk	Total
Amount of Syringe Used (ml)	N	0	0	0
	Mean ± SD	0.0 ± 0.00	0.0 ± 0.00	0.0 ± 0.00
	Median	0.0	0.0	0.0
	Min, Max	0, 0	0, 0	0, 0
Injection Techniques Used	N (%) Serial Puncture	0 (0.0%)	0 (0.0%)	0 (0.0%)
	N (%) Antegrade Linear Threading	0 (0.0%)	0 (0.0%)	0 (0.0%)
	N (%) Retrograde Linear Threading	0 (0.0%)	0 (0.0%)	0 (0.0%)
Depth of Injection	N (%) Submucosa	0 (0.0%)	0 (0.0%)	0 (0.0%)
	N (%) Intramuscular	0 (0.0%)	0 (0.0%)	0 (0.0%)
	N (%) Superficial Dermis	0 (0.0%)	0 (0.0%)	0 (0.0%)
	N (%) Mid Dermis	0 (0.0%)	0 (0.0%)	0 (0.0%)
	N (%) Deep Dermis	0 (0.0%)	0 (0.0%)	0 (0.0%)
	N (%) Subcutaneous Fat	0 (0.0%)	0 (0.0%)	0 (0.0%)
Investigator Ease of Use Assessment	Mean ± SD	0.0 ± 0.00	0.0 ± 0.00	0.0 ± 0.00
	Median	0.0	0.0	0.0
	Min, Max	0, 0	0, 0	0, 0

Investigator Ease of Use Assessment based on the Numerical Rating Scale (NRS): 0 (Not Easy) to 10 (Most Easy).
Source: Listing 16.2.5.1
O:\Studies\Prollenium\SYM 2018-03\Biometrics\Programs\Tables\xxx.sas ran on Month Day, Year at hh:mm on data from Month, Day, Year.

Note:

Table 14.3.1.1 will be used as the shell for the following table:

Table 14.3.1.2 – Exposure to Study Product and Investigator Ease of Use Assessment (Lower Lips) at Visit 1/Day 1 Retreatment

Table 14.3.1.3 – Exposure to Study Product and Investigator Ease of Use Assessment (Perioral Areas) at Visit 1/Day 1 Retreatment

Table 14.3.2.1 – Treatment-Emergent Adverse Events (TEAEs) Related to Vascular Injections/Visual Events by MedDRA System Organ Class and Preferred Term

System Organ Class Preferred Term	Reported by Subject or PI	PRO 2018-02 PN40082 (N=xx)	PRO 2018-02 Restylane Silk (N=xx)	Total (N=xx)
Subjects with at Least One Injection-Site or Visual TEAE	By Subject	0 (0%)	0 (0%)	0 (0%)
	By PI	0 (0%)	0 (0%)	0 (0%)
	Total	0 (0%)	0 (0%)	0 (0%)
Class 1	By Subject	0 (0%)	0 (0%)	0 (0%)
	By PI	0 (0%)	0 (0%)	0 (0%)
	Total	0 (0%)	0 (0%)	0 (0%)
Term 1	By Subject	0 (0%)	0 (0%)	0 (0%)
	By PI	0 (0%)	0 (0%)	0 (0%)
	Total	0 (0%)	0 (0%)	0 (0%)
…				
…				

Counts reflect numbers of subjects reporting one or more TEAE related to vascular injections/visual event that map to the MedDRA (version x x) system organ class/preferred term. At each level of summarization (system organ class or preferred term), subjects reporting more than one event are counted only once.
Source: Listing 16.2.7.1.1
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Table 14.3.2.2 – Treatment-Emergent Adverse Events (TEAEs) Related to Vascular Injections/Visual Events by MedDRA System Organ Class, Preferred Term, and Severity

System Organ Class Preferred Term	Severity	PRO 2018-02 PN40082 (N=xx)	PRO 2018-02 Restylane Silk (N=xx)	Total (N=xx)
Subjects with at Least One Injection-Site or Visual TEAE	Mild	0 (0%)	0 (0%)	0 (0%)
	Moderate	0 (0%)	0 (0%)	0 (0%)
	Severe	0 (0%)	0 (0%)	0 (0%)
Class 1	Mild	0 (0%)	0 (0%)	0 (0%)
	Moderate	0 (0%)	0 (0%)	0 (0%)
	Severe	0 (0%)	0 (0%)	0 (0%)
Term 1	Mild	0 (0%)	0 (0%)	0 (0%)
	Moderate	0 (0%)	0 (0%)	0 (0%)
	Severe	0 (0%)	0 (0%)	0 (0%)
…				
…				

Counts reflect numbers of subjects reporting one or more TEAE related to vascular injections/visual event that map to the MedDRA (version x x) system organ class/preferred term. At each level of summarization (system organ class or preferred term), subjects reporting more than one event are counted only once (under the greatest reported severity).
Source: Listing 16.2.7.1.1
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Table 14.3.2.3 – Treatment-Emergent Adverse Events (TEAEs) Related to Vascular Injections/Visual Events by MedDRA System Organ Class, Preferred Term, and Causality

System Organ Class Preferred Term	Causality	PRO 2018-02 PN40082 (N=xx)	PRO 2018-02 Restylane Silk (N=xx)	Total (N=xx)
Subjects with at Least One Injection-Site or Visual TEAE	Unlikely	0 (0%)	0 (0%)	0 (0%)
	Related*	0 (0%)	0 (0%)	0 (0%)
Class 1	Unlikely	0 (0%)	0 (0%)	0 (0%)
	Related*	0 (0%)	0 (0%)	0 (0%)
Term 1	Unlikely	0 (0%)	0 (0%)	0 (0%)
	Related*	0 (0%)	0 (0%)	0 (0%)
…				
…				

*Related category includes Possibly and Probably Related.
Counts reflect numbers of subjects reporting one or more TEAE related to vascular injections/visual event that map to the MedDRA (version x x) system organ class/preferred term. At each level of summarization (system organ class or preferred term) subjects reporting more than one event are only counted once (under the most likely relationship to study medication).
Source: Listing 16.2.7.1.1
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Table 14.3.2.4 – Treatment-Emergent Adverse Events (TEAEs) Related to Vascular Injections/Visual Events by MedDRA System Organ Class, Preferred Term, and Number of Injections

	PRO 2018-02 PN40082		PRO 2018-02 Restylane Silk	
System Organ Class Preferred Term	1 Injection (N=xx)	2 Injections (N=xx)	1 Injection (N=xx)	2 Injections (N=xx)
Class 1	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Term 1	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Term 2	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Class 2	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Term 1	0 (0%)	0 (0%)	0 (0%)	0 (0%)

…

Note: All retreated subjects received 1more injection of PN40082 in this open-label study.
Counts reflect numbers of subjects reporting one or more TEAE related to vascular injections/visual event that map to the MedDRA (version x x) system organ class/preferred term. At each level of summarization (system organ class or preferred term), subjects reporting more than one event are counted only once.
Source: Listing 16.2.7.1.1
O:\Studies\Prollenium\SYM 2018-03\Biometrics\Programs\Tables\xxx.sas ran on Month Day, Year at hh:mm on data from Month Day, Year.

Table 14.3.2.5 – Treatment-Emergent Adverse Events (TEAEs) Related to Vascular Injections/Visual Events by MedDRA System Organ Class, Preferred Term, and Fitzpatrick Skin Type (FST)

System Organ Class Preferred Term	Treatment Group In PRO 2018-02	FST I % (n/N)[1]	FST II % (n/N)[1]	FST III % (n/N)[1]	Pooled FST I-III % (n/N)[1]	FST IV % (n/N)[1]	FST V % (n/N)[1]	FST VI % (n/N)[1]	Pooled FST IV-VI % (n/N)[1]
Subjects with at Least One Injection-Site or Visual TEAE	PN40082	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)
	Restylane Silk	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)
	Total	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)
Class 1	PN40082	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)
	Restylane Silk	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)
	Total	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)
Term 1	PN40082	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)
	Restylane Silk	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)
	Total	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)
…									
…									
…									

[1] N = number of subjects of a certain FST in the associated treatment group; n = number of subjects of a certain FST in the associated treatment group reporting TEAE.
Counts reflect numbers of subjects reporting one or more TEAE related to vascular injections/visual event that map to the MedDRA (version x x) system organ class/preferred term. At each level of summarization (system organ class or preferred term), subjects reporting more than one event are counted only once.
Source: Listing 16.2.7.1.1
O:\Studies\Prollenium\SYM 2018-03\Biometrics\Programs\Tables\xxx.sas ran on Month Day, Year at hh:mm on data from Month Day, Year.

Table 14.3.2.6 – Most Frequently Occurring Treatment-Emergent Adverse Events (TEAEs) Related to Vascular Injections/Visual Events by MedDRA Preferred Term

System Organ Class Preferred Term	PRO 2018-02 PN40082 (N=xx)	PRO 2018-02 Restylane Silk (N=xx)	Total (N=xx)
Class 1			
Term 1	0 (0%)	0 (0%)	0 (0%)
Term 2	0 (0%)	0 (0%)	0 (0%)
Class 2			
Term 1	0 (0%)	0 (0%)	0 (0%)
…			
…			

Most frequently occurring TEAEs related to vascular injections/visual event are those that were reported by 5% or more of the total retreated subjects.
Counts reflect numbers of subjects reporting one or more TEAE related to vascular injections/visual event that map to the MedDRA (version x x) system organ class/preferred term. At each level of summarization (preferred term) subjects reporting more than one event are only counted once.
Source: Listing 16.2.7.1.1
O:\Studies\Prollenium\SYM 2018-03\Biometrics\Programs\Tables\xxx.sas ran on Month Day, Year at hh:mm on data from Month Day, Year.

Table 14.3.2.7 – Severity of Most Frequently Occurring Treatment-Emergent Adverse Events (TEAEs) Related to Vascular Injections/Visual Events by MedDRA Preferred Term

Preferred Term	Treatment Group In PRO 2018-02	Events % (n/N)[1]	Mild % (n/N)[2]	Moderate % (n/N)[2]	Severe % (n/N)[2]
Term 1	PN40082	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)
	Restylane Silk	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)
	Total	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)
Term 2	PN40082	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)
	Restylane Silk	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)
	Total	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)
…					
…					
…					

Most frequently occurring TEAEs related to vascular injections/visual event are those that were reported by 5% or more of the total retreated subjects.
[1] Denominator is the number of TEAEs related to vascular injections/visual event reported by all subjects who received the corresponding treatment.
[2] Denominator for percentages by severity is the number of subjects with respective TEAEs after receiving the corresponding treatment. Numerator (count of subjects) is based on the rule that subjects reporting more than one same incidence associated with a treatment arm are counted only once for the treatment arm under the greatest reported severity.
Source: Listing 16.2.7.1.1
O:\Studies\Prollenium\SYM 2018-03\Biometrics\Programs\Tables\xxx.sas ran on Month Day, Year at hh:mm on data from Month Day, Year.

Table 14.3.2.8 – Duration of Most Frequently Occurring Treatment-Emergent Adverse Events (TEAEs) Related to Vascular Injections/Visual Events by MedDRA Preferred Term

Preferred Term	Treatment Group In PRO 2018-02	Events % (n/N)[1]	<7 Days % (n/N)[2]	7-30 Days % (n/N)[2]	>30 Days % (n/N)[2]
Term 1	PN40082	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)
	Restylane Silk	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)
	Total	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)
Term 2	PN40082	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)
	Restylane Silk	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)
	Total	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)
…					
…					
…					

Most frequently occurring TEAEs related to vascular injections/visual event are those that were reported by 5% or more of the total retreated subjects.
[1] Denominator is the number of TEAEs related to vascular injections/visual event reported by all subjects who received the corresponding treatment.
[2] Denominator for percentages by severity is the number of subjects with respective TEAEs after receiving the corresponding treatment. Numerator (count of subjects) is based on the rule that subjects reporting more than one same incidence associated with a treatment arm are counted only once for the treatment arm under the longest duration.
Source: Listing 16.2.7.1.1
O:\Studies\Prollenium\SYM 2018-03\Biometrics\Programs\Tables\xxx.sas ran on Month Day, Year at hh:mm on data from Month Day, Year.

Table 14.3.2.9 – Overall Summary of Treatment-Emergent Adverse Events (TEAEs) Related to Vascular Injections/Visual Events

	PRO 2018-02 PN40082		PRO 2018-02 Restylane Silk		Total	
	Subjects[1] (N=xx)	Events[2] (N=xx)	Subjects[1] (N=xx)	Events[2] (N=xx)	Subjects[1] (N=xx)	Events[2] (N=xx)
Overall	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Duration						
Less than 1 week	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Between 1 week and 1 month (30 days)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
More than 1 month (30 days)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Severity						
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Moderate	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Causality						
Treatment-related*	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not treatment-related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Outcome						
Resolved	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Improved	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Stabilized	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Worsened	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Unchanged	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Treatment Required (Action Taken)						
None	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Study treatment interrupted/discontinued	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Non-drug therapy	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
New OTC or Rx drug added	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Hospitalized (includes ER visits)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

[1] Denominator is the number of subjects who received the corresponding treatment.
[2] Denominator is the number of adverse events reported by subjects who received the corresponding treatment.
*Treatment-related includes Possibly and Probably Related.
For Severity and Causality, subjects reporting more than one TEAE related to vascular injections/visual event associated with a treatment arm are counted only once for the treatment arm under the greatest reported severity and most likely causality, respectively.

For Duration, Outcome and Treatment Required (Action Taken), at each level of the categories, subjects reporting more than one TEAE related to vascular injections/visual event associated with a treatment arm are counted only once for the treatment arm at that category level.
Source: Listing 16.2.7.1.1
O:\Studies\Prollenium\SYM 2018-03\Biometrics\Programs\Tables\xxx.sas ran on Month Day, Year at hh:mm on data from Month Day, Year.

Note:

Tables 14.3.2.1, 14.3.2.2, 14.3.2.3, 14.3.2.4 will be used as the shell for the following tables:

Table 14.3.3.1 – Treatment-Emergent Adverse Events (TEAEs) Excluding Vascular Injections/Visual Events by MedDRA System Organ Class and Preferred Term

Table 14.3.3.2 – Treatment-Emergent Adverse Events (TEAEs) Excluding Vascular Injections/Visual Events by MedDRA System Organ Class, Preferred Term, and Severity

Table 14.3.3.3 – Treatment-Emergent Adverse Events (TEAEs) Excluding Vascular Injections/Visual Events by MedDRA System Organ Class, Preferred Term, and Causality

Table 14.3.3.4 – Treatment-Emergent Adverse Events (TEAEs) Excluding Vascular Injections/Visual Events by MedDRA System Organ Class, Preferred Term, and Number of Injections

With footnote regarding data source change to “Source: Listing 16.2.7.1.2”.

Table 14.3.4.1 – Lip Function and Lip Sensation Tests by Visit

Study Visit	Category	PRO 2018-02 PN40082	PRO 2018-02 Restylane Silk	Total
Was the subject able to sip liquid through a straw?				
Visit 1/Day 1 (Prior to injection)	N	0	0	0
	n (%) Yes	0 (0%)	0 (0%)	0 (0%)
Visit 2/Month 1	N	0	0	0
	n (%) Yes	0 (0%)	0 (0%)	0 (0%)
Visit 3/Month 2	N	0	0	0
	n (%) Yes	0 (0%)	0 (0%)	0 (0%)
Was the subject able to feel sensation of a 0.4G monofilament at three points on the upper lip and three points on the lower lip?				
Visit 1/Day 1 (Prior to injection)				
…				
Was the subject able to feel sensation of a cotton wisp at three points on the upper lip and three points on the lower lip?				
Visit 1/Day 1 (Prior to injection)				
…				

Source: Listing 16.2.4.8
O:\Studies\Prollenium\SYM 2018-03\Biometrics\Programs\Tables\xxx.sas ran on Month Day, Year at hh:mm on data from Month, Day, Year.

Table 14.3.4.2 – Lip Texture Evaluation by Visit

Study Visit	Category	PRO 2018-02 PN40082	PRO 2018-02 Restylane Silk	Total
Visit 1/Day 1 (Prior to injection)	N	0	0	0
	n (%) Normal	0 (0%)	0 (0%)	0 (0%)
	n (%) Abnormal	0 (0%)	0 (0%)	0 (0%)
	- n (%) Abnormal: Mild	0 (0%)	0 (0%)	0 (0%)
	- n (%) Abnormal: Moderate	0 (0%)	0 (0%)	0 (0%)
	- n (%) Abnormal: Severe	0 (0%)	0 (0%)	0 (0%)
Visit 2/Month 1	...			
	…			
Visit 3/Month 2				

Source: Listing 16.2.4.9
O:\Studies\Prollenium\SYM 2018-03\Biometrics\Programs\Tables\xxx.sas ran on Month Day, Year at hh:mm on data from Month, Day, Year.

Note:

Table 14.3.4.2 will be used as the shell for the following table:

Table 14.3.4.3 – Lip Firmness Evaluation by Visit

Table 14.3.4.4 – Lip Symmetry Evaluation by Visit

Table 14.3.4.5 – Lip Movement/Function Evaluation by Visit

Study Visit	Category	PRO 2018-02 PN40082	PRO 2018-02 Restylane Silk	Total
Visit 1/Day 1 (Prior to injection)	N	0	0	0
	n (%) Normal – Subject's ability to pucker lips	0 (0%)	0 (0%)	0 (0%)
	n (%) Normal – Subject's ability to blow with lips	0 (0%)	0 (0%)	0 (0%)
	n (%) Normal – Subject's ability to pronounce words that begin with "W"	0 (0%)	0 (0%)	0 (0%)
Visit 2/Month 1	...			
	…			
Visit 3/Month 2				

Source: Listing 16.2.4.8
O:\Studies\Prollenium\SYM 2018-03\Biometrics\Programs\Tables\xxx.sas ran on Month Day, Year at hh:mm on data from Month, Day, Year.

Subject Listings

Listing 16.2.1.1 – Subject Disposition

Site-Subject	Treatment in PRO 2018-02	Subject Disposition	Date Completed or Discontinued	Reason, if discontinued

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Listing 16.2.1.2 – Dates of Visits

Site-Subject	Treatment in PRO 2018-02	Visit 1/ Day 1 (Baseline)	Telephone Call Day 3 (±2 days) [Day #]	Telephone Call Day 14 (±2 days) [Day #]	Visit 2/ Month 1 Day 28 (±2 days) [Day #]	Visit 3/ Month 2 Day 56 (±4 days) [Day #]	Telephone Call Day 168 (±7 days) [Day #]	No. of UVs: Unscheduled Visit(s) [Day #]

Day # (Study Days) = Visit Date - Baseline (Visit 1) Date +1.
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Listing 16.2.2.1 – Informed Consent and Inclusion/Exclusion Criteria

Site-Subject	Treatment in PRO 2018-02	Subject signed informed consent form (ICF)?	Date ICF Signed	Inclusion #1	Inclusion #2	Inclusion #3	Exclusion #1

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Listing 16.2.2.2 – Comments

Site-Subject	Treatment in PRO 2018-02	Date of Comments	CRF Page Number	Comment(s)	Initials

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Listing 16.2.4.1 – Demographics

Site-Subject	Subject Initials	Treatment in PRO 2018-02	Age (yrs)	Sex	Race	Ethnicity	Fitzpatrick Skin Type

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Listing 16.2.4.2 – Brief Physical Examination at Baseline

Site-Subject	Treatment in PRO 2018-02	Height (inches)	Weight (lbs)	Physical Examination		
				Heart	Lungs	Abdomen

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Listing 16.2.4.3 – Medical History Findings

Site-Subject	Treatment in PRO 2018-02	Medical System	Diagnosis/Procedure	Onset Date	Stop Date	Concomitant Medication?
		xxxxxxx	xxxxxxxxxxx	-----1997	Ongoing	No

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Listing 16.2.4.4 – Prior and Concomitant Medications/Treatments

Site-Subject	Treatment in PRO 2018-02	If Used on Face	WHO Class // WHO Name //Medication	Indication	Start Date [Day #]	Stop Date [Day #]	Dosage	Freq.	Route
		QD1	XXXXXXXXX // XXXXXXXXXX XXX // XXXXXXXX	XXXXXXX	01JAN05 [3]	Ongoing	xxxxx	xxxx	xxx

Note: Medications coded using the WHO Drug Dictionary, version xxx.
Day # is calculated from baseline (Visit 1) date. Day 1 is the baseline date while Day -1 is the day prior to the baseline visit. L=Left side of the face, R=Right side of the face.
O:\Studies\ Prollenium\SYM 2018-03\Biometrics\Programs\Listing\xxx.sas ran on Month Day Year at hh:mm on data from Month Day, Year.

Listing 16.2.4.5 – Non-Pharmacological Interventions (NPIs)

Site-Subject	Treatment in PRO 2018-02	If Used on Face	Non-Pharmacological Intervention	Indication	Start Date [Day #]	Stop Date [Day #]	Dosage	Freq.	Route
		QD1,QD2	XXXXXXXXX XXX XXXXXXXX	XXXXXXX	01JAN05 [3]	Ongoing	xxxxx	xxxx	xxx

Day # is calculated from baseline (Visit 1) date. Day 1 is the baseline date while Day -1 is the day prior to the baseline visit. L=Left side of the face, R=Right side of the face.
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Listing 16.2.4.6 – Vital Signs and Urine Pregnancy Test at Baseline

Site-Subject	Treatment in PRO 2018-02	Sitting Systolic BP (mmHg)	Sitting Diastolic BP (mmHg)	Heart Rate (bpm)	Oral Temperature (°F)	Respiratory Rate (breath/min)	Urine Pregnancy Test	
							Test Results	Test Date

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Listing 16.2.4.7 – Vision Evaluation

Site-Subject	Treatment in PRO 2018-02	Study Visit (Time Point)	Subject wearing corrective lenses?	Confrontational Visual Field Results (Specify if abnormal), Assessed by	Ocular Visual Field Results (Specify if abnormal), Assessed by	Snellen Visual Acuity Score (SVAS) Left Eye	SVAS Right Eye	SVAS Assessed by	Vision at Post-Baseline Visit: Changed significantly from PRO 2018-02 baseline?	Vision at Post-Baseline Visit: If yes, the study ophthalmologist contacted?

Listing 16.2.4.8 – Lip Function, Lip Sensation and Lip Movement/Function Tests

Site-Subject	Treatment in PRO 2018-02	Study Visit (Time Point)	Able to sip liquid through a straw?	Assessor of Lip Function	Able to feel sensation of a cotton wisp?	Able to feel sensation of a 0.4G monofilament	Assessor of Lip Sensation	Ability to pucker lips	Ability to blow with lips	Ability to pronounce words that begin with "W"	Assessor of Lip Movement /Function

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Listing 16.2.4.9 – Lip Texture, Lip Firmness and Lip Symmetry Evaluations

Site-Subject	Treatment in PRO 2018-02	Study Visit (Time Point)	Lip Texture		Lip Firmness		Lip Symmetry	
			Normal or Abnormal (severity)	Evaluator	Normal or Abnormal (severity)	Evaluator	Normal or Abnormal (severity)	Evaluator

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Listing 16.2.5.1 – Treatment Administration at Visit 1/Day 1

Site-Subject	Treatment in PRO 2018-02	Injection placed successfully?	Site of Injection	Time of Injection	Amount of Syringe Used (ml)	Injection Techniques Used	Depth of Injection	Initials Who Performed Injection	Investigator Ease of Use Assessment	Evaluator

Investigator Ease of Use Assessment assess on the Numerical Rating Scale (NRS): 0 (Not Easy) to 10 (Most Easy).
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Listing 16.2.6.1 – Efficacy Evaluations of Lip Fullness Grading Scale and Perioral Lines at Rest Severity Scale

Site-Subject	Treatment in PRO 2018-02	Study Visit	Lip Fullness Grading Scale (LFGS) Rating				Perioral Lines at Rest Severity Scale (POL)			
			Overall Rating	Upper Lip Rating	Lower Lip Rating	Assessed by	Overall Rating	Upper Lip Rating	Lower Lip Rating	Assessed by
xx-xxx	R. Silk	Visit 1 (PRO 2018-02) Visit 1 (Retreatment)								

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Listing 16.2.6.2 – Efficacy Evaluations of Subject Satisfaction with Lips, Swelling and Global Aesthetic Improvement

Site-Subject	Treatment in PRO 2018-02	Study Visit	Subject Satisfaction with Lips VAS	Swelling Assessment		Patient Global Aesthetic Improvement (pGAI)	Investigator Global Aesthetic Improvement (iGAI)	
				Grade	Performed By		Score	Performed By

Listing 16.2.7.1.1 – Adverse Events (Related to Vascular Injections/Visual Events)

Site-Subject	Trt. in PRO 2018-02	FST	Reported by	System Organ Class// Preferred Term// Verbatim Term	Start Date Time [Day #]	Stop Date Time [Day #]	Severity Causality Outcome	Where on face Rel. to injection? Vision related?	Action Taken[1]	SAE
xx-xxx	R. Silk	III	Subj/Diary	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS//	01JAN2019	04JAN2019	MILD	QD1, QD3	3,4	N
				INJECTION SITE SWELLING//	13:25	08:30	PROBABLY	Y		
				SWELLING ON FACE	2	5	STABLIZED	N		

Day # is calculated from baseline (Visit 1) date. Day 1 is the baseline date while Day -1 is the day prior to the baseline visit.
[1] Action Taken: 1=None, 2=Study treatment interrupted/discontinued, 3=Non-drug therapy, 4=New OTC or Rx drug added, 4=Hospitalized
O:\Studies\ Prollenium\SYM 2018-03\Biometrics\Programs\Listing\xxx.sas ran on Month Day Year at hh mm on data from Month Day, Year.

Listing 16.2.7.1.2 – Adverse Events (Excluding Vascular Injections/Visual Events)

Site-Subject	Trt. in PRO 2018-02	FST	Reported by	System Organ Class// Preferred Term// Verbatim Term	Start Date [Day #]	Stop Date [Day #]	Severity Causality Outcome	Where on face	Action Taken[1]	SAE
xx-xxx	R. Silk	III	Subj/Diary	NERVOUS SYSTEM DISORDERS// HEADACHE // HEADACHE	01JAN2019 2	04JAN2019 5	MILD UNLIKELY STABLIZED	QD1,QD3	1	N

Day # is calculated from baseline (Visit 1) date. Day 1 is the baseline date while Day -1 is the day prior to the baseline visit.
[1] Action Taken: 1=None, 2=Study treatment interrupted/discontinued, 3=Non-drug therapy, 4=New OTC or Rx drug added, 4=Hospitalized
O:\Studies\ Prollenium\SYM 2018-03\Biometrics\Programs\Listing\xxx.sas ran on Month Day Year at hh mm on data from Month Day, Year.

Note:

Repeat Listings 16.2.7.1.1 and 16.2.7.1.2 for AEs that led to study treatment interrupted/Discontinued and Serious AEs –

Listing 16.2.7.2.1 – Adverse Events (Related to Vascular Injections/Visual Events) Leading to Study Treatment Interrupted/Discontinued

Listing 16.2.7.2.2 – Adverse Events (Excluding Vascular Injections/Visual Events) Leading to Study Treatment Interrupted/Discontinued

Listing 16.2.7.3.1 – Serious Adverse Events (Related to Vascular Injections/Visual Events)

Listing 16.2.7.3.2 – Serious Adverse Events (Excluding Vascular Injections/Visual Events)

Listing 16.2.7.4 – Adverse Events (Related to Vascular Injections/Visual Events) Lasted more than 30 Days